FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: A-200SL-OR3-C

Product name(s): LEPTOSAR 200 SL

Chemical active substance:

acetamiprid, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: CIECH Sarzyna S.A.

Submission date: 23/02/2021

MS Finalisation date: 01/07/2022

Version history

When	What
February 2021	First submission for product authorization in Poland
May 2021	Dossier sent for evaluation
December 2021	zRMS finalised evaluation
July 2022	Final version prepared by zRMS after Commenting period

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Evaluator comments:
The text highlighted in grey was provided by the evaluator.

6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on LEPTOSAR 200 SL *

Product name and code	A-200SL-OR3-C/ LEPTOSAR 200 SL
Formulation type	SL
Active substance(s) (incl. content)	acetamipryd, 200 g/L
Function	insecticide
Product already evaluated as the 'representative formulation' during the approval of the active substance(s)	No
Product previously evaluated in another MS according to Uniform Principles	No

* Information on the detailed composition of LEPTOSAR 200 SL can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification and labelling with regard to toxicological data is proposed for the preparation:

Table 6.1-2: Justified proposals for classification and labelling for LEPTOSAR 200 SL according to Regulation (EC) No 1272/2008

Hazard class(es), categories	Acute Tox. 4 Skin Sens. 1B Eye Irrit. 2 Repr. 2
Hazard pictograms or Code(s) for hazard pictogram(s)	GHS07 GHS08
Signal word	Warning
Hazard statement(s)	H302 - Harmful if swallowed H317- May cause an allergic skin reaction. H319 – Causes serious eye irritation. H361 d - Suspected of damaging fertility or the unborn child
Precautionary statement(s)	P201, P261, P264, P270, P280, P308+P313
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for LEPTOSAR 200 SL

	Result	PPE / Risk mitigation measures
Operators	Acceptable	- ~~Workwear~~ Coverall and gloves - green house use (tomato, aubergine paprika) - Workwear and gloves - apple, pear, quince, medlar, cherry, peach, nectarine, apricot, plum, hazelnut, walnut, tobacco, common osier,

	Result	PPE / Risk mitigation measures
		purple willow - ~~Workwear – all other uses~~ ~~–~~ Workwear, gloves and drift reduction - oilseed rape, mustard, turnip rape, flax, hemp, sunflower, opium poppy, wheat, rye, triticale, maize, sorghum, millet, soybean and pumpkin - Workwear, ~~gloves~~ and closed cabin - forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees plantations
Workers	Acceptable	- Workwear (oilseed rape, mustard, turnip rape, ~~cereals~~, wheat, rye, triticale, maize, sorghum, millet, flax, hemp, sunflower, opium poppy) - Workwear and gloves (soybean, pumpkin, apple, pear, quince, medlar, cherry, peach, nectarine, apricot, plum, hazelnut, walnut, forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees plantations, tobacco, purple willow, common osier, greenhouse uses - tomato, aubergine, paprika)
Residents	Acceptable	None
Bystanders	Acceptable	~~None~~ 5m buffer zone - apple, pear, quince, medlar, cherry, peach, nectarine, apricot, plum, hazelnut, walnut, ~~forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees plantations,~~ tobacco, purple willow, common osier 5m buffer zone and drift reduction - forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees plantations

No unacceptable risk for operators, workers, residents and bystanders was identified when the product is used as intended and depending on crop to be treated, provided that the PPE/ risk mitigation measures stated in Table 6.1-3 are applied.

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and residents/bystanders is presented in the following table.

Table 6.1-4 Critical uses and overall conclusion of exposure assessment

1	2	3	4	5	6	7	8	9	10			
Use-No.*	**Crops and situation (e.g. growth stage of crop)**	**F, Fn, Fpn G, Gn, Gpn or I ****	**Application**		**Application rate**		**PHI (d)**	**Remarks:** **(e.g. safener/synergist (L/ha))** **critical gap for operator, worker, resident or bystander exposure based on [Exposure model]**	**Acceptability of exposure assessment**			
			Method / Kind **(incl. application technique *****	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season**	**Max. application rate kg as/ha** **a) per use** **b) per crop/ season**	**Water L/ha** **min / max**			**Operator**	**Worker**	**Residents**	**Bystander**
1	Oilseed rape (BBCH ~~17~~ 20-71) Mustard Turnip rape (BBCH 20-71)	F	Spraying, LCTM	a) 1 b) 1	a) 0.060 b) 0.060	200 – 400	-	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for	R	A	A	A

1	2	3	4	5	6	7	8	9	10			
2	Wheat, ~~Barley~~ Rye Tritacale ~~Rye~~ (BBCH 30-65)	F	Spraying, LCTM	a) 1 b) 1	a) 0.040 b) 0.040	200 - 400	-	plant protection products; EFSA Journal 2014;12(10):3874	R	A	A	A
3	Maize , Sorghum Millet (BBCH 51-75)	F	Spraying, LCTM	a) 1 b) 1	a) 0.060 b) 0.060	300 - 500	-		R	A	A	A
4.	Soybean (BBCH 11-65)	F	Spraying, LCTM	a) 1 b) 1	a) 0.060 b) 0.060	200 - 500	-		R	R	A	A
5.	Pumpkin (BBCH ~~21-69~~ 50-65)	F	Spraying, LCTM	a) 1 b) 1	a) 0.060 b) 0.060	200 - 500	-		R	R	A	A
6.	Tomato, auber-gine paprika (BBCH 20-~~s~~ 89)	G	Spraying LCHH	a) 1 b) 1	a) 0.060 b) 0.060	300 - 750	3		R	R	A	A
7.	Apple, pear, quince, medlar, Cherry, peach, nectarine, apricote, plum (BBCH ~~1-~~ 51-87) Huzelnut, walnut (BBCH 1 50 ~~1~~-65)	F	Spraying, HCTM	a) 1 b) 2 (7 d)	a) 0.025 b) 0.050	200 - 750	14		R	R	A	R
8.	Forest and ornamental nurseries plants, restock-ings, afforesta-tions and forest trees' seed plantations; Christmas trees grown on plantations (BBCH 11-69)	F	Spraying, HCTM	a) 1 b) 1	a) 0.050 b) 0.050 Finally agreed max. dose: a) 0.040 b) 0.040	200 - 400	n.a.		R	R	A	R

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

*** e.g. LC: low crops, HC: high crop, TM: tractor-mounted, HH: hand-held

Explanation for column 10 "Acceptability of exposure assessment"

A	Exposure acceptable without PPE / risk mitigation measures
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable/ Evaluation not possible

Data gaps

No gaps

Noticed data gaps are:

6.2 Toxicological Information on Active Substance(s)

Information regarding classification of the active substances and on EU endpoints and critical areas of concern identified during the EU review are given in Table 6.2-1.

Table 6.2-1: Information on active substance(s)

	Acetamiprid
Common Name	acetamiprid
CAS-No.	135410-20-7
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories: Acute Tox 4, H302 Code(s) for hazard pictogram(s): ~~H302~~ GHS07 Signal word: Warning Hazard statement(s): Harmful if swallowed Precautionary statement(s) P264 Wash hands thoroughly after handling P270 Do not eat, drink or smoke when using this product P301+ P312~~+P330~~ IF SWALLOWED: Call a doctor if you feel unwell. ~~Rinse mouth.~~ P330 Rinse mouth
Additional C&L proposal	According to RAC Opinion (04/05/2020) the following toxicological classification is for acetamipri~~y~~d proposed: Acute tox. 3, H301, Repr. 2, H361d
Agreed EU endpoints	
AOEL systemic	0.025 mg/kg bw/d
AAOEL systemic	0.025 mg/kg bw/d
Reference	EFSA Journal 2016;14(11):4610, SANTE/10502/2017 Rev 4; 13 December 2017
Conditions to take into account/critical areas of concern with regard to toxicology	
According to Review Report/EFSA Conclusion for acetamiprid	None.

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for LEPTOSAR 200 SL is given in the following tables. Full summaries of studies on the product that have not been previously considered within an EU peer review process are described in detail in Appendix 2.

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for LEPTOSAR 200 SL

Type of test, species, model system (Guideline)	**Result**	**Acceptability**	**Classification (acc. to the criteria in Reg. 1272/2008)**	**Reference**
LD_{50} oral, rat	No study submitted	Yes	**Acute Tox. 4, H302** Classification based on composition of the product (estimation method -additivity	Appendix 2

			formula)	
LD_{50} dermal, rat	No study submitted	Yes	No classification based on composition of the product (estimation method - additivity formula)	Appendix 2
LC_{50} inhalation, rat	No study submitted	Yes	No classification based on composition of the product (estimation method - additivity formula)	Appendix 2
	Not submitted, not necessary. Justification presented in Appendix 2			
Skin irritation~~, model system~~	No study submitted	Yes	No classification based on composition of the product (estimation method - additivity formula)	Appendix 2
Eye irritation~~, model system~~	No study submitted	Yes	**Eye Dam. 2, H319** Classification based on composition of the product (estimation method -additivity formula)	Appendix 2
Skin sensitisation, guinea pig/mouse	No study submitted ~~Estimation based on composition of the product (additivity formula)~~	Yes / No / Supplementary	**Skin Sens 1B, H317** Classification based on composition of the product (estimation method -additivity formula)	Appendix 2
Supplementary studies for combinations of plant protection products	No data – not required		-	-

Table 6.3-2: Additional toxicological information relevant for classification/labelling of LEPTOSAR 200 SL

	Substance (concentration in product, % w/w)	**Classification of the substance (acc. to the criteria in Reg. 1272/2008)**	**Reference**	**Classification of product (acc. to the criteria in Reg. 1272/2008)**
Toxicological properties of active substance(s) (relevant for classification of product)	Acetamiprid (17.24% (w/w)	H361d	RAC Opinion dated 04/05/2020	H361d
Toxicological properties of non-active substance(s) (relevant for classification of product)	component reffered in Confidential section" present in concentration below limit defined in CLP	H304	Reg. 1272/2008 / MSDS**/ Section C	Not required

	Substance (concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Reg. 1272/2008)	Reference	Classification of product (acc. to the criteria in Reg. 1272/2008)
Further toxicological information	-	-	-	-

* Please use concentration range or concentration limit (e.g. 1-10% or > 1%) as provided in MSDS.
** Material safety data sheet by the applicant

6.4 Toxicological Evaluation of Groundwater Metabolites

zRMS comment	The concentration of acetamiprid metabolites in groundwater are predicted to occur below the trigger value of 0.1 µg/L, therefore, the relevance assessment of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is not required.

All metabolite concentrations are predicted to stay below 0.1 µg/L – no groundwater assessment is required.

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in LEPTOSAR 200 SL are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in LEPTOSAR 200 SL

	Acetamiprid	
	Value	**Reference**
Concentrate	10%	EFSA Guidance on dermal absorption (EFSA Journal 2017;15(6):4873)
Dilutions	50%	

6.5.1 Justification for proposed values - acetamiprid

No data on dermal absorption for acetamiprid in LEPTOSAR 200 SL is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal ~~2012; 10(4):2665~~ 2017;15(6):4873) are presented in the following table.

Table 6.5-2: Default dermal absorption rates for acetamiprid

	Value	Justification for value	Acceptability of justification
Concentrate	10%	Default dermal absorption value from EFSA Journal 2017;15(6):4873 for the soluble concentrate (SL)	Accepted
Dilution	50%	Default dermal absorption value from EFSA Journal 2017;15(6):4873 for dilution of the soluble concentrate (SL)	Accepted

6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

Table 6.6-1: Product information and toxicological reference values used for exposure assessment

Product name and code	LEPTOSAR 200 SL
Formulation type	SL
Category	Insecticide
Active substance(s) (incl. content)	**acetamiprid** 200 g/L
AOEL systemic	0.025 mg/kg bw/d
AAOEL systemic	0.025 mg/kg bw/d
Inhalation absorption	100%
Oral absorption	100%
Dermal absorption	Concentrate: 10% Dilution: 50% (Defaults)

6.6.1 Selection of critical use(s) and justification

The critical GAP(s) used for the exposure assessment of the plant protection product are shown in Table 6.1-4. A list of all intended uses within the zone is given in Part B, Section 0.

Justification

Critical GAP was selected based on the highest application rates recommended in the minimum water volume in each category group of crop, i.e.:

- 1 x 0.3 L of product/ ha eq. to 1 x 60 g of acetamiprid/ha for oilseed rapes, mustard, turnip rape (Oilseeds scenario);
- 1 x 0.2 L of product/ ha eq. to 1 x 40 g of acetamiprid/ha for cereals (wheat, rye, triticale) (Cereals scenario);
- 1 x 0.3 L of product/ ha eq. to 1 x 60 g of acetamiprid/ha for maize ~~and sugar maize~~, sorghum, millet (Cereals scenario);
- 1 x 0.3 L of product/ ha eq. to 1 x 60 g of acetamiprid/ha for soybean and pumpkin (Legume vegetables scenario/ Brassica vegetables scenario);
- 2 x 0.125 L of product/ ha eq. to 2 x 25 g of acetamiprid/ha (7 days interval between treatments) for apple, pear, quince, medlar (Pome fruits scenario), cherry, peach, nectarine, apricot, plum (Stone fruits scenario), hazelnut, walnut (~~Pome fruits/Stone fruits/~~Tree nuts scenario)
- 1 x 0.25 L of product/ ha eq. to 1 x 50 g of acetamiprid/ha for forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees plantations (Pome fruits scenario) – finally agreed max. dose is 1 x 0.20 L of product/ ha eq to 1 x 40 g of acetamiprid/ha

- 1 x 0.3 L of product/ ha eq. to 1 x 60 g of acetamiprid/ha for tomato, aubergine and paprika in a greenhouse scenario

For minor crops not mentioned above, such as:
- flax, hemp, sunflower and poppy the oil seed scenario is also the umbrella assessment
- tobacco, common osier and purple willow, the pome fruit scenario with 2 applications per season covers the appropriate risk assessment.

6.6.2 Operator exposure (KCP 7.2.1)

Comments of zRMS:	The operator exposure calculations for the proposed uses of LEPTOSAR 200 SL conducted by the Applicant were completed by Evaluator. The Applicant presented calculations only for longer term operator exposure, but Evaluator calculated also acute operator exposure, because the reference value acutely toxic active substance (AAOEL) for acetamiprid is determined (EFSA Journal 2016;14(11):4610, SANTE/10502/2017 Rev 4; 13 December 2017) (results in Table 6.6 3b). Longer term exposure The predicted longer term operator exposure to LEPTOSAR 200 SL applied outdoors via tractor mounted boom sprayer to low and high crops is within acceptable limit when the operator uses workwear. In greenhouses the exposure is acceptable when the operator uses workwear and gloves. Acute exposure The predicted acute operator exposure to LEPTOSAR 200 SL applied outdoors via tractor mounted boom sprayer to low crops is within acceptable limit when the operator uses workwear and gloves and also drift reduction technology is applied. When the product is applied outdoors via tractor mounted boom sprayer outdoors to high crops the exposure is acceptable when the operator uses workwear and gloves in all intended uses except and additionally the cabin is closed in case of use the product in Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations /Christmas trees plantation. **Conclusions:** The operator exposure to LEPTOSAR 200 SL applied outdoors via tractor mounted boom sprayer to **low crops** is within acceptable limit when the operator uses **workwear, gloves and also drift reduction technology is applied.** The operator exposure to LEPTOSAR 200 SL applied outdoors via tractor mounted boom sprayer to **high crops** is within acceptable limit when the operator uses **workwear and gloves** in all intended uses and additionally the **cabin is closed** in the case of the use of the product in Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations /Christmas trees plantation. Due to changes in the finally agreed max. doses for use in Forsest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations /Christmas trees plantation (1×40 g a.s./ha instead of 1×50 g a.s./ha) **gloves are no more needed for this use.** In **greenhouses** the exposure is acceptable when the operator uses **workwear and gloves.**

6.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances dur-

ing application of LEPTOSAR 200 SL according to the critical use(s) is presented in Table 6.6-2. The outcome of the estimation is presented in **Błąd! Nie można odnaleźć źródła odwołania.** (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-2: Exposure models for intended uses

Critical use(s)	Oilseed rape, mustard, turnip rape (max. 1 x 0.3 L product/ha) Cereals (wheat, rye, triticale) (max. 1 x 0.2 L product/ha) Maize, sorghum, millet (max. 1 x 0.3 L product/ha) Soybean and pumpkin (max. 1 x 0.3 L product/ha) Apple, pear, quince, medlar (Pome fruits), cherry, peach, nectarine, apricot, plum (stone fruits) and hazelnut, walnut (tree nuts) (max. 2 x 0.125 L product/ha, 7 d interval) Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees plantations (Pome fruits) (max. 1 x 0.25 L product/ha) - finally agreed max. 1 x 0.20 L of product/ ha Greenhouse use (tomato, aubergine, paprika) (max. 1 x 0.3 L of product/ ha)
Model(s)	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015 Dutch greenhouse model: Van Golstein Brouwers, Y.G.C., Marquart, J. and Van Hemmen, J.J. (1996). Assessment of occupational exposure to pesticides in agriculture. Part IV. Protocol for the use of generic exposure data. TNO Nutrition and Food Research Institute, The Netherlands. TNO Report V 96.120

Table 6.6-3a: Estimated operator exposure (longer term exposure)

		Acetamiprid	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
EFSA calculator Tractor mounted boom spray application outdoors to low crops – **oilseed rape, mustard, turnip rape**			
Application rate		1 x 0.060 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.0379825	**151.93**
	Work wear (arms, body and legs covered) M/L and A	0.0232014	92.81
EFSA calculator Tractor mounted boom spray application outdoors to low crops – **cereals (wheat, rye, triticale)**			
Application rate		1 x 0.040 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.0276730	**110.69**
	Work wear (arms, body and legs covered) M/L and A	0.0167240	66.90
EFSA calculator Tractor mounted boom spray application outdoors to low crops – **maize, sorghum, millet**			
Application rate		1 x 0.060 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.0379825	**151.93**
	Work wear (arms, body and legs covered) M/L and A	0.0232014	92.81

EFSA calculator Tractor mounted boom spray application outdoors to low crops – **soybean (legume vegetables), pumpkin (brassica vegetables scenario)**			
Application rate		1 x 0.060 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.0379825	**151.93**
	Work wear (arms, body and legs covered) M/L and A	0.0232014	92.81
EFSA calculator Tractor mounted boom spray application outdoors to high crops: **apple, pear, quince, medlar (Pome fruits), cherry, peach, nectarine, apricot, plum (stone fruits) and hazelnut, walnut (tree nut)**			
Application rate		2 x 0.025 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.0324971	**129.99**
	Work wear (arms, body and legs covered) M/L and A	0.0121467	48.59
EFSA calculator Tractor mounted boom spray application outdoors to high crops: **Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations /Christmas trees plantation (pome fruit scenario)**			
Application rate		1 x 0.050 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.0621250	**248.50**
	Work wear (arms, body and legs covered) M/L and A	0.0222576	89.3
Application rate		1 x 0.040 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.0503986	201.59
	Work wear (arms, body and legs covered) M/L and A	0.0183049	73.22
Spraying in greenhouses Dutch greenhouse model **Tomato, aubergine, paprika**			
Application rate		1 x 0.060 kg a.s./ha	
Spray application Body weight: 60 kg	Total exposure (Inhalation and dermal exposure without PPE)	0.101	**404~~%~~**
	Total exposure (Inhalation exposure without PPE, dermal exposure - gloves and coveralls)	0.011	44~~%~~

Table 6.6-3b: Estimated operator exposure (acute exposure)

		Acetamiprid	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AAOEL**
EFSA calculator Tractor mounted boom spray application outdoors to low crops – **oilseed rape, mustard, turnip rape**			
Application rate		1 x 0.060 kg a.s./ha	
Spray application (AOEM**;** 95th percentile) Body weight: 60 kg	Potential exposure	0.2906358	**1162.54**
	Work wear (arms, body and legs covered) M/L and A	0.1156441	**462.58**
	Work wear (arms, body and legs covered) + gloves, M/L and A	0.0357331	**142.93**
	Work wear (arms, body and legs covered) + gloves, M/L and A + **drift reduction**	0.0042272	16.91
EFSA calculator Tractor mounted boom spray application outdoors to low crops – **cereals (wheat, rye, triticale)**			
Application rate		1 x 0.040 kg a.s./ha	
Spray application (AOEM**;** 95th percentile) Body weight: 60 kg	Potential exposure	0.2382608	**953.04**
	Work wear (arms, body and legs covered) M/L and A	0.0848963	**339.59**
	Work wear (arms, body and legs covered) + gloves, M/L and A	0.0330583	**132.23**
	Work wear (arms, body and legs covered) + gloves, M/L and A + **drift reduction**	0.0031287	12.51
EFSA calculator Tractor mounted boom spray application outdoors to low crops – **maize, sorghum, millet**			
Application rate		1 x 0.060 kg a.s./ha	
Spray application (AOEM**;** 95th percentile) Body weight: 60 kg	Potential exposure	0.2906358	**1162.54**
	Work wear (arms, body and legs covered) M/L and A	0.1156441	**462.58**
	Work wear (arms, body and legs covered) + gloves, M/L and A	0.0357331	**142.93**
	Work wear (arms, body and legs covered) + gloves, M/L and A + **drift reduction**	0.0042272	16.91
EFSA calculator Tractor mounted boom spray application outdoors to low crops – **soybean (legume vegetables), pumpkin (brassica vegetables scenario)**			
Application rate		1 x 0.060 kg a.s./ha	
Spray application	Potential exposure	0.2906358	**1162.54**

(AOEM; 95th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.1156441	**462.58**
	Work wear (arms, body and legs covered) + gloves, M/L and A	0.0357331	**142.93**
	Work wear (arms, body and legs covered) + gloves, M/L and A + **drift reduction**	0.0042272	16.91
EFSA calculator Tractor mounted boom spray application outdoors to high crops: **apple, pear, quince, medlar (Pome fruits), cherry, peach, nectarine, apricot, plum (stone fruits) and hazelnut, walnut (tree nut)**			
Application rate		2 x 0.025 kg a.s./ha	
Spray application (AOEM; 95th percentile) Body weight: 60 kg	Potential exposure	0.2261657	**904.66**
	Work wear (arms, body and legs covered) M/L and A	0.0393331	**157.33**
	Work wear (arms, body and legs covered) + gloves, M/L and A	0.0182599	73.04
EFSA calculator Tractor mounted boom spray application outdoors to high crops: **Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations /Christmas trees plantation (pome fruit scenario)**			
Application rate		1 x 0.050 kg a.s./ha	
Spray application (AOEM; 95th percentile) Body weight: 60 kg	Potential exposure	0.3866660	**1546.66**
	Work wear (arms, body and legs covered) M/L and A	0.0753441	**301.38**
	Work wear (arms, body and legs covered) + gloves, M/L and A	0.0360644	**144.26**
	Work wear (arms, body and legs covered) + gloves, M/L and A + **closed cab**	0.0058272	23.31
Application rate		1 x 0.040 kg a.s./ha	
Spray application (AOEM; 95th percentile) Body weight: 60 kg	Potential exposure	0.3235931	**1294.37**
	Work wear (arms, body and legs covered) M/L and A	0.0610672	**244.27**
	Work wear (arms, body and legs covered) M/L and A + closed cab	0.0235294	**94.12**

6.6.2.2 Measurement of operator exposure

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and consideration of the above mentioned ~~personal protective equipment (PPE)~~ risk mitigation measures, a study to provide measurements of operator exposure was not necessary and was therefore not performed.

6.6.3 Worker exposure (KCP 7.2.3)

Comments of zRMS:	The worker exposure calculations for the proposed uses of LEPTOSAR 200 SL conducted by the Applicant using the EUROPOEM II model and the EFSA calculator and presented in Table 6.6-5 are accepted. In the case of oilseed rape, mustard, turnip rape, wheat, rye, triticale, maize, sorghum, millet, flax, hemp, sunflower and opium poppy the worker exposure undertaking crop inspection activity is within acceptable limit assuming workers are wearing workwear (arms, body and legs covered). The obtained values calculated for these intended uses in both models are below the AOEL values. In the case of soybean, pumpkin, apple, pear, quince, medlar, cherry, peach, nectarine, apricot, plum, hazelnut, walnut, forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees plantations, tobacco, purple willow, common osier and greenhouse uses (tomato, aubergine paprika) the worker exposure undertaking crop inspection activity is within acceptable limit assuming workers are wearing workwear (arms, body and legs covered) and gloves. The obtained values calculated for these intended uses in both models are below the AOEL values. As a standard rule, crops treated by LEPTOSAR 200 SL should not be re-entered before spray deposit on leaf surfaces has completely dried.

6.6.3.1 Estimation of worker exposure

Table 6.6-4 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with LEPTOSAR 200 SL according to the critical use(s). Outcome of the estimation is presented in Table 6.6- (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-4: Exposure models for intended uses

Critical use(s)	Oilseed rape, mustard, turnip rape (max. 1 x 0.3 L product/ha) Cereals (wheat, rye, triticale) (max. 1 x 0.2 L product/ha) Maize, sorghum, millet (max. 1 x 0.3 L product/ha) Soybean and pumpkin (max. 1 x 0.3 L product/ha) ~~Pumpkin (max. 1 x 0.3 L product/ha)~~ Apple, pear, quince, medlar (Pome fruits), cherry, peach, nectarine, apricot, plum (stone fruits) and hazelnut, walnut (tree nuts) (max. 2 x 0.0125 L product/ha; 7 d interval) Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees plantations (Pome fruits) (max. 1 x 0.25 L product/ha) finally agreed max. 1 x 0.20 L of product/ ha Green house use (tomato, aubergine, paprika) (max. 1 x 0.3 L product/ha)
Model(s)	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015 Post-Application Exposure of Workers to Pesticides in Agriculture – Report of the Re-entry Working Group. EUROPOEM II Project, FAIR3-CT96-1406. December 2002

Table 6.6-5: Estimated worker exposure (longer term exposure)

		Acetamiprid	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
EFSA calculator Inpsection, irrigation Outdoor Work rate: 2 hours/day DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha MAF: n.a.			
Application rate		**Oilseed rape, mustard, turnip rape** 1 x 0.06 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm²/person/h	0.0375000	150.00
	Work wear (arms, body and legs covered) TC: 1400 cm²/person/h	0.0042000	16.80
	Work wear (arms, body and legs covered) and gloves TC: xxx cm²/person/h	n.a.	n.a.
EFSA calculator Inpsection, irrigation Outdoor Work rate: 2 hours/day DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha MAF: n.a.			
Application rate		**Cereals (wheat, rye, triticale)** 1 x 0.04 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm²/person/h	0.0250000	**100**

	Work wear (arms, body and legs covered) TC: 1400 cm^2/person/h	0.0028000	11.20
	Work wear (arms, body and legs covered) and gloves TC: xxx cm^2/person/h	n.a.	n.a.
EFSA calculator Inpsection, irrigation Outdoor Work rate: 2 hours/day DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha MAF: n.a.			
Application rate		**Maize, sorghum, millet** 1 x 0.06 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm^2/person/h	0.0375000	**150**
	Work wear (arms, body and legs covered) TC: 1400 cm^2/person/h	0.004200	16.80
	Work wear (arms, body and legs covered) and gloves TC: xxx cm^2/person/h	n.a.	n.a.
EFSA calculator Reaching, picking Outdoor Work rate: 8 hours/day DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha MAF: n.a.			
Application rate		**Soybean, pumpkin** 1 x 0.06 kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm^2/person/h	0.0696000	**278.40**
	Work wear (arms, body and legs covered) TC: 2500 cm^2/person/h	0.0300000	**120.00**
	Work wear (arms, body and legs covered) and gloves TC: 580 cm^2/person/h	0.0069600	~~27.84~~ 24
EFSA calculator Searching, reaching, picking Outdoor Work rate: 8 hours/day DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha MAF: 1.9			
Application rate		**Apple, pear, quince, medlar (Pome fruits), cherry, peach, nectarine, apricot, plum (stone fruits) and hazelnut, walnut (tree nut)** 2 x 0.025 kg a.s./ha (7 d interval)	
Body weight: 60 kg	Potential	0.2082001	**832.80**

	TC: 22500 cm^2/person/h		
	Work wear (arms, body and legs covered) TC: 4500 cm^2/person/h	0.0416400	**166.56**
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm^2/person/h	0.0208200	83.28
EFSA calculator Searching, reaching, picking Outdoor Work rate: 8 hours/day DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha MAF: n.a.			
Application rate		**Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations /Christmas trees plantation (Pome fruits)** 1 x 0.05 kg a.s./ha	
Body weight: 60 kg	Potential TC: 22500 cm^2/person/h	0.2250000	**900**
	Work wear (arms, body and legs covered) TC: 4500 cm^2/person/h	0.0450000	**180**
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm^2/person/h	0.0225000	90
Application rate		**Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations /Christmas trees plantation (Pome fruits)** 1 x 0.04 kg a.s./ha	
Body weight: 60 kg	Potential TC: 22500 cm^2/person/h	0.1800000	**720**
	Work wear (arms, body and legs covered) TC: 4500 cm^2/person/h	0.0360000	**144**
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm^2/person/h	0.0180000	72
EFSA calculator Reaching, picking Indoor Work rate: 8 hours/day DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha MAF: n.a.			
Application rate		**Greenhouse use - Tomato, aubergine paprika** 1 x 0.06 kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm^2/person/h	0.0696000	**278.40**
	Work wear (arms, body and legs covered) TC: 2500 cm^2/person/h	0.0300000	**120.00**

	Work wear (arms, body and legs covered) and gloves TC: 580 cm^2/person/h	0.0069600	27.84
EUROPOEM II Work rate: 2 hours/day DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha MAF: n.a.			
Application rate		**Oilseed rape, mustard, turnip rape** 1 x 0.06 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm^2/person/h	0.0375~~00~~	**150**
	Work wear (arms, body and legs covered) TC: 1400 cm^2/person/h	0.00420~~0~~	~~16.80~~ 17
	Work wear (arms, body and legs covered) and gloves TC: 1400 cm^2/person/h PPE factor dermal: 5	0.00080~~0~~3	3
EUROPOEM II Work rate: 2 hours/day DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha MAF: n.a.			
Application rate		**Cereals (wheat, rye, triticale)** 1 x 0.04 kg a.s./ha (365 d interval)	
Body weight: 60 kg	Potential TC: 12500 cm^2/person/h	0.02500~~0~~	**100**
	Work wear (arms, body and legs covered) TC: 1400 cm^2/person/h	0.00280	11
	Work wear (arms, body and legs covered) and gloves TC: 1400 cm^2/person/h PPE factor dermal: 5	0.00056	2
EUROPOEM II Work rate: 2 hours/day DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha MAF: n.a.			
Application rate		**Maize, sorghum, millet** 1 x 0.06 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm^2/person/h	0.03750	**150**
	Work wear (arms, body and legs covered) TC: 1400 cm^2/person/h	0.00420	17
	Work wear (arms, body and legs covered) and gloves TC: 1400 cm^2/person/h PPE factor dermal: 5	0.00083~~3~~	3
EUROPOEM II			

Work rate: 8 hours/day DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha MAF: n.a.			
Application rate		**Soybean, pumpkin** 1 x 0.06 kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm²/person/h	0.06960	**278**
	Work wear (arms, body and legs covered) TC: 2500 cm²/person/h	0.03000	**120**
	Work wear (arms, body and legs covered) and gloves TC: 2500 cm²/person/h PPE factor dermal: 5	0.00600	24
EUROPOEM II Work rate: 8 hours/day DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha MAF: 1.9			
Application rate		**Apple, pear, quince, medlar (Pome fruits), cherry, peach, nectarine, apricot, plum (stone fruits) and hazelnut, walnut (tree nut)** 2 x 0.025 kg a.s./ha (7 d interval)	
Body weight: 60 kg	Potential TC: 22500 cm²/person/h	0.213875	**855**
	Work wear (arms, body and legs covered) TC: 4500 cm²/person/h	0.043275	**171**
	Work wear (arms, body and legs covered) and gloves TC: 4500 cm²/person/h PPE factor dermal: 5	0.009855	34
EUROPOEM II Work rate: 8 hours/day DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha MAF: n.a.			
Application rate		**Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations /Christmas trees plantation (Pome fruits)** 1 x 0.05 kg a.s./ha	
Body weight: 60 kg	Potential TC: 22500 cm²/person/h	0.22500	**900**
	Work wear (arms, body and legs covered) TC: 4500 cm²/person/h	0.04500	**180**
	Work wear (arms, body and legs covered) and gloves TC: 4500 cm²/person/h PPE factor dermal: 5	0.00900	36
EUROPOEM II Work rate: 8 hours/day			

DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha MAF: n.a.			
Application rate		**Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations /Christmas trees plantation (Pome fruits)** 1 x 0.04 kg a.s./ha	
Body weight: 60 kg	Potential TC: 22500 cm²/person/h	0.18000	**720**
	Work wear (arms, body and legs covered) TC: 4500 cm²/person/h	0.03600	**144**
	Work wear (arms, body and legs covered) and gloves TC: 4500 cm²/person/h PPE factor dermal: 5	0.0072	29
EUROPOEM II Reaching, picking Indoor Work rate: 8 hours/day DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha MAF: n.a.			
Application rate		**Greenhouse use - Tomato, aubergine paprika** 1 x 0.06 kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm²/person/h Inhalation exposure without PPE	0.07003	**280**
	Work wear (arms, body and legs covered) TC: 2500 cm²/person/h Inhalation exposure without PPE	0.03043	**122**
	Work wear (arms, body and legs covered) and gloves TC: 2500 cm²/person/h PPE factor dermal: 5 Inhalation exposure without PPE	0.006~~1~~05	24~~.0~~

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

Not relevant, default value 3 µg/cm²/kg a.s./ha was applied for calculations

6.6.3.3 Measurement of worker exposure

Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mention PPE, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

6.6.4 Resident and bystander exposure (KCP 7.2.2)

Comments of zRMS:	The resident and bystander exposure calculations for the proposed uses of LEPTOSAR 200 SL conducted by the Applicant were completed by Evaluator. The Applicant presented calculations only for long term resident exposure, but Evaluator calculated also acute exposure for bystanders, because the reference value acutely toxic active substance (AAOEL) for acetamiprid is determined (EFSA Journal 2016;14(11):4610, SANTE/10502/2017 Rev 4; 13 December 2017) (results in Table 6.6 3b). Resident exposure: In all intended uses except greenhouses the predicted longer term exposure of a child and adult resident resulting from spray drift, vapour, surface deposits, re-entry into treated crops and sum of all pathways calculated for acetamiprid is within the acceptable limit provided that in the case of apple, pear, quince, medlar, cherry, peach, nectarine, apricot, plum, hazelnut, walnut and forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees plantations the buffer zone of 5 m is applied. Bystander exposure: In all intended uses except greenhouses the predicted acute exposure of a child and adult bystander resulting from spray drift, vapour, surface deposits and entry into treated crops calculated for acetamiprid is within acceptable limit provided that in the case of apple, pear, quince, medlar, cherry, peach, nectarine, apricot, plum, hazelnut, walnut and forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees plantations the buffer zone of 5 m is applied. Additionally, in the case of the forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees plantation only the use of the **drift reduction technology** reduces spray drift to the acceptable level (79.51% of AAOEL for child, 63.61% taking into consideration the finally agreed max. dose of 1×40 g a.s./ha instead of 1×50 g a.s./ha). Conclusions: In the case of greenhouses it can be expected that the risk assessment for all outdoor uses will cover the exposure resulting from the indoor use of LEPTOSAR 200 SL. In all remain intended uses the predicted resident and bystander exposure calculated for acetamiprid is within acceptable limit provided that in the case of apple, pear, quince, medlar, cherry, peach, nectarine, apricot, plum, hazelnut, walnut and forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees plantations the buffer zone of 5 m is applied. Additionally, in the case of the forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees plantations only the use of the **drift reduction technology** reduces spray drift to the acceptable level for bystanders.

6.6.4.1 Estimation of resident and bystander exposure

The acute exposure assessment for bystanders covers the exposure that a resident could reasonably be expected to incur in a single day. Therefore, there is no need for a separate acute risk assessment for residents.

~~No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the poten-~~

~~tial to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.~~

Table 6.6-6 shows the exposure model(s) used for estimation of resident and bystander exposure to acetamiprid. The outcome of the estimation is presented in Table 6.6-7 (longer term resident and acute bystander exposure). Detailed calculations are in Appendix 3.

In case of **green house use the resident/bystander risk assessment** has not been performed separately. It can be expected that risk assessment for all outdoor uses will be much higher and thus, will cover the exposure resulting from the indoor use of LEPTOSAR 200 SL.

Table 6.6-6: Exposure models for intended uses

Critical use(s)	Oilseed rape, mustard, turnip rape (max. 1 x 0.3 L product/ha) Cereals (wheat, rye, triticale) (max. 1 x 0.2 L product/ha) Maize, sorghum, millet (max. 1 x 0.3 L product/ha) Soybean and pumpkin (max. 1 x 0.3 L product/ha) ~~Pumpkin (max. 1 x 0.3 L product/ha)~~ Apple, pear, quince, medlar (Pome fruits), cherry, peach, nectarine, apricot, plum (stone fruits) and hazelnut, walnut (tree nuts) (max. 2 x 0.0125 L product/ha; 7 d interval) Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees plantations (Pome fruits) (max. 1 x 0.25 L product/ha) finally agreed max. 1 x 0.20 L of product/ ha
Model(s)	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

Table 6.6-~~6~~7: Estimated resident and bystander exposure (longer term and acute exposure)

		Acetamiprid	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL or AAOEL**
Tractor mounted boom spray application outdoors to low crops Buffer zone: 2-3 (m) Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 365 days MAF: n.a.			
Number of applications and application rate		**Oilseed rape, mustard, turnip rape** 1 x 0.06 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0040287	16.11
	Vapour (75th perc.)	0.0010700	4.28
	Deposits (75th perc.)	0.0004855	1.94
	Re-entry (75th perc.)	0.0050625	20.25
	Sum (mean)	0.0076811	30.72
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.000964	3.86
	Vapour (75th perc.)	0.000230	0.92

	Deposits (75th perc.)	0.0002044	0.82
	Re-entry (75th perc.)	0.0028125	11.25
	Sum (mean)	0.0030801	12.32
Bystander child Body weight: 10 kg	Spray drift (95th perc.)	0.0091356	36.54
	Vapour (95th perc.)	0.0010700	4.28
	Surface deposits (95th perc.)	0.0014535	5.81
	Entry into treated crops (95th perc.)	0.0050625	20.25
Bystander adult Body weight: 60 kg	Spray drift (95th perc.)	0.0024830	9.93
	Vapour (95th perc.)	0.0002300	0.92
	Surface deposits (95th perc.)	0.0006163	2.47
	Entry into treated crops (95th perc.)	0.0028125	11.25
Tractor mounted boom spray application outdoors to low crops Buffer zone: 2-3 (m) Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 365 days MAF: n.a.			
Number of applications and application rate		**Cereals, (wheat, rye, triticale)** 1 x 0.04 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.002686	10.74
	Vapour (75th perc.)	0.001070	4.28
	Deposits (75th perc.)	0.000324	1.29
	Re-entry (75th perc.)	0.003375	13.50
	Sum (mean)	0.005477	21.91
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0006427	2.57
	Vapour (75th perc.)	0.0002300	0.92
	Deposits (75th perc.)	0.0001363	0.55
	Re-entry (75th perc.)	0.0018750	7.50
	Sum (mean)	0.0021301	8.52
Bystander child Body weight: 10 kg	Spray drift (95th perc.)	0.0060904	~~36.54~~ 24.36
	Vapour (95th perc.)	0.0010700	4.28
	Surface deposits (95th perc.)	0.0009690	3.88
	Entry into treated crops (95th perc.)	0.0033750	13.50
Bystander adult Body weight: 60 kg	Spray drift (95th perc.)	0.0016553	6.62
	Vapour (95th perc.)	0.0002300	0.92
	Surface deposits (95th perc.)	0.00041108	1.64
	Entry into treated crops	0.0018750	7.50

	(95th perc.)		
Tractor mounted boom spray application outdoors to low crops Buffer zone: 2-3 (m) Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 365 days MAF: n.a.			
Number of applications and application rate		**Maize, sorghum, millet** 1 x 0.06 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.002686	10.74
	Vapour (75th perc.)	0.001070	4.28
	Deposits (75th perc.)	0.000486	1.94
	Re-entry (75th perc.)	0.005063	20.25
	Sum (mean)	0.006941	27.77
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.000643	2.57
	Vapour (75th perc.)	0.000230	0.92
	Deposits (75th perc.)	0.000204	0.82
	Re-entry (75th perc.)	0.002813	11.25
	Sum (mean)	0.002927	11.71
Bystander child Body weight: 10 kg	Spray drift (95th perc.)	0.0060904	24.36
	Vapour (95th perc.)	0.0010700	4.28
	Surface deposits (95th perc.)	0.0014535	5.81
	Entry into treated crops (95th perc.)	0.0050625	20.25
Bystander adult Body weight: 60 kg	Spray drift (95th perc.)	0.0016553	6.62
	Vapour (95th perc.)	0.0002300	0.92
	Surface deposits (95th perc.)	0.0006163	2.47
	Entry into treated crops (95th perc.)	0.0028125	11.25
Tractor mounted boom spray application outdoors to low crops Buffer zone: 2-3 (m) Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 365 days MAF: n.a.			
Number of applications and application rate		**Soybean, pumpkin** 1 x 0.06 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0040287	16.11
	Vapour (75th perc.)	0.001070	4.28
	Deposits (75th perc.)	0.000486	1.94
	Re-entry (75th perc.)	0.005063	20.25
	Sum (mean)	0.0076811	30.72
Resident adult	Drift (75th perc.)	0.0009640	3.86

Body weight: 60 kg	Vapour (75th perc.)	0.000230	0.92
	Deposits (75th perc.)	0.000204	0.82
	Re-entry (75th perc.)	0.002813	11.25
	Sum (mean)	0.0030801	12.32
Bystander child Body weight: 10 kg	Spray drift (95th perc.)	0.0091356	36.54
	Vapour (95th perc.)	0.0010700	4.28
	Surface deposits (95th perc.)	0.0014535	5.81
	Entry into treated crops (95th perc.)	0.0050625	20.25
Bystander adult Body weight: 60 kg	Spray drift (95th perc.)	0.0024830	9.93
	Vapour (95th perc.)	0.0002300	0.92
	Surface deposits (95th perc.)	0.0006163	2.47
	Entry into treated crops (95th perc.)	0.0028125	11.25
Tractor mounted boom spray application outdoors to high crops Buffer zone: 5 (m) Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 7 days MAF: 1.9			
Number of applications and application rate		**Apple, pear, quince, medlar (Pome fruits), cherry, peach, nectarine, apricot, plum (stone fruits) and hazelnut, walnut (tree nuts) 2 x 0.025 kg a.s./ha**	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0086767	34.71
	Vapour (75th perc.)	0.0010700	4.28
	Deposits (75th perc.)	0.0010556	4.22
	Re-entry (75th perc.)	0.0039038	15.62
	Sum (mean)	0.0106695	42.68
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0048133	19.25
	Vapour (75th perc.)	0.0002300	0.92
	Deposits (75th perc.)	0.0004444	1.78
	Re-entry (75th perc.)	0.0021688	8.68
	Sum (mean)	0.0054351	21.74
Bystander child Body weight: 10 kg	Spray drift (95th perc.)	0.0198773	79.51
	Vapour (95th perc.)	0.0010700	4.28
	Surface deposits (95th perc.)	0.0026227	10.49
	Entry into treated crops (95th perc.)	0.0039038	15.62
Bystander adult Body weight: 60 kg	Spray drift (95th perc.)	0.0110279	44.11
	Vapour (95th perc.)	0.0002300	0.92

	Surface deposits (95th perc.)	0.0011120	4.45
	Entry into treated crops (95th perc.)	0.0021688	8.68
Tractor mounted boom spray application outdoors to high crops Buffer zone: 5 (m) Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 365 days MAF: n.a.			
Number of applications and application rate		**Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees plantations (Pome fruits)** 1 x 0.05 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0173533	69.41
	Vapour (75th perc.)	0.0010700	4.289
	Deposits (75th perc.)	0.0011408	4.56
	Re-entry (75th perc.)	0.0042188	16.88
	Sum (mean)	0.0166891	66.76
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0096267	38.51
	Vapour (75th perc.)	0.0002300	0.92
	Deposits (75th perc.)	0.0004803	1.92
	Re-entry (75th perc.)	0.0023438	9.38
	Sum (mean)	0.0087481	34.99
Bystander child Body weight: 10 kg	Spray drift (95th perc.)	0.0397546	**159.02**
	Spray drift (95th perc.) + **drift reduction**	0.0198773	79.51
	Vapour (95th perc.)	0.0010700	4.28
	Vapour (95th perc.) + **drift reduction**	0.0010700	4.28
	Surface deposits (95th perc.)	0.0028343	11.34
	Surface deposits (95th perc.) + **drift reduction**	0,0014172	5.67
	Entry into treated crops (95th perc.)	0.0042188	16.88
	Entry into treated crops (95th perc.) + **drift reduction**	0.0042188	16.88
Bystander adult Body weight: 60 kg	Spray drift (95th perc.)	0.0220558	88.22
	Spray drift (95th perc.) + **drift reduction**	0.0110279	44.11
	Vapour (95th perc.)	0.0002300	0.92
	Vapour (95th perc.) + **drift reduction**	0.0002300	0.92

	Surface deposits (95th perc.)	0.0012017	4.81
	Surface deposits (95th perc.) + **drift reduction**	0.0006008	2.40
	Entry into treated crops (95th perc.)	0.0023438	9.38
	Entry into treated crops (95th perc.) + **drift reduction**	0.0023438	9.38
Tractor mounted boom spray application outdoors to high crops Buffer zone: 5 (m) Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 365 days MAF: n.a.			
Number of applications and application rate		**Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees plantations (Pome fruits)** 1 x 0.04 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0138827	55.53
	Vapour (75th perc.)	0.0010700	4.28
	Deposits (75th perc.)	0.0009127	3.65
	Re-entry (75th perc.)	0.0033750	13.50
	Sum (mean)	0.0135653	54.26
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0077013	30.81
	Vapour (75th perc.)	0.0002300	0.92
	Deposits (75th perc.)	0.0003842	1.54
	Re-entry (75th perc.)	0.0018750	7.50
	Sum (mean)	0.0070445	28.18
Bystander child Body weight: 10 kg	Spray drift (95th perc.)	0.0318037	**127.21**
	Vapour (95th perc.)	0.0010700	4.28
	Surface deposits (95th perc.)	0.0022675	9.07
	Entry into treated crops (95th perc.)	0.0033750	13.50
Bystander adult Body weight: 60 kg	Spray drift (95th perc.)	0.0176447	70.58
	Vapour (95th perc.)	0.0002300	0.92
	Surface deposits (95th perc.)	0.0009614	3.85
	Entry into treated crops (95th perc.)	0.0018750	7.50
Bystander child Body weight: 10 kg	Spray drift (95th perc.) + drift reduction	0.0159018	63.61
	Vapour (95th perc.) + drift reduction	0.0010700	4.28

	Surface deposits (95th perc.) + drift reduction	0.0011337	4.53
	Entry into treated crops (95th perc.) + drift reduction	0.0033750	13.50
Bystander adult Body weight: 60 kg	Spray drift (95th perc.) + drift reduction	0.0088223	35.29
	Vapour (95th perc.) + drift reduction	0.0002300	0.92
	Surface deposits (95th perc.) + drift reduction	0.0004807	1.92
	Entry into treated crops (95th perc.) + drift reduction	0.0018750	7.50

6.6.4.2 Measurement of resident and/or bystander exposure

Since the resident and/or bystander exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for acetamiprid will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures. A study to provide measurements of resident/bystander exposure was not necessary and was therefore not performed.

6.6.5 Combined exposure

Not relevant. The product contains only one active substance.

Appendix 1 Lists of data considered in support of the evaluation

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

Bridging is not necessary since the toxicological potential of ~~HAKSAR TOP 565 SG~~ LEPTOSAR 200 SL can be predicted on the basis of toxicological data available for active substances and co-formulants included in composition of above-mentioned product.

Comments of zRMS:	Accepted

A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	The classification of the component containing 3 co-formulants with acute oral classification is determined in MSDS, therefore there is no need to use for calculation the particular compounds, which are not at significant concentrations. Ultimately, these particular compounds have no impact on final result. The calculation method and final result are accepted and according to the calculation the product LEPTOSAR 200 SL should be classified as Acute Tox. 4 with the H302 statement.

Acute oral toxicity value (ATE mix) can be estimated according to principles of Regulation 1272/2008. p. 3.1.3.6.1 (additivity formula) as follows:

$$\frac{100}{ATE_{mix}} = \sum_n \frac{C_i}{ATE_i}$$

Where:

C_i – concentration of ingredient I (% w/w or % v/v)
I – the individual ingredient from 1 to n
n – the number of ingredients
ATE_i – Acute Toxicity Estimate of ingredient i.

Calculations take~~s~~ into account data for components which are classified to acute oral toxicity class and significant concentration. According to RAC Opinion the active substance acetamiprid is classified as Acute Tox. 3. H301. Its concentration in the product is equal to 17.24% and its lowest LD_{50} is 140 mg/kg bw (according to EFSA Journal 2016;14(11):4610).
In addition there are 3 other co-formulants with acute oral classification and the H301 (Acute Tox. 3) or H302 (Acute Tox. 4) statement.
Their concentration in the product is equal to 0.000005%, 0.0000005% and 0.000000015%, respectively.

Taking all above into account the ATE_{mix} for the whole formulation is therefore:

$$\text{The } ATE_{mix} = \frac{100}{\frac{17.24}{140} + \frac{0.000005}{500} + \frac{0.0000005 + 0.000000015}{100}} = 813 \text{ mg/kg bw}$$

The estimated value ATE_{mix} of acute oral toxicity for LEPTOSAR 200 SL is equal to 813 mg/kg bw and thus. The product should be classified as Acute Tox. 4 with the H302 statement.
No additional studies are required.

A 2.3 Acute percutaneous (dermal) toxicity (KCP 7.1.2)

Comments of zRMS:	The classification of the component containing 3 co-formulants with acute dermal classification is determined in MSDS, therefore there is no need to use for calculation the particular compounds, which are not at significant concentrations. Ultimately, these particular compounds have no impact on final result. Taking into account the classification of the co-formulants of the product LEPTOSAR 200 SL the product should not be classified with regards to the acute dermal toxicity.

Acute dermal toxicity value (ATE mix) can be estimated according to principles of Regulation 1272/2008. P. 3.1.3.6.1 (additivity formula) as follows:

$$\frac{100}{ATE_{mix}} = \sum_n \frac{C_i}{ATE_i}$$

Where:

C_i – concentration of ingredient I (% w/w or % v/v)
I – the individual ingredient from 1 to n
n – the number of ingredients
ATE_i – Acute Toxicity Estimate of ingredient i.

Calculations takes into account data for components which are classified to acute dermal toxicity class and significant concentration.
There are 3 components (co-formulants) in LEPTOSAR 200 SL with acute dermal classification and the H311 (Acute Tox. 3) or H312 (Acute Tox. 4) statement.
Their concentration in the product is equal to 0.000005%, 0.0000005% and 0.000000015%, respectively.

Taking all above into account the ATE_{mix} for the whole formulation is therefore:

$$\text{The } ATE_{mix} = \frac{100}{\frac{0.000005}{1100} + \frac{0.0000005 + 0.000000015}{300}} >>> 2000 \text{ mg/kg bw}$$

The estimated value ATE_{mix} of acute ~~oral~~ dermal toxicity for LEPTOSAR 200 SL is far above 2000 mg/kg bw
and thus. The product should not be classified with regards to acute dermal toxicity.
No additional studies are required.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	The classification of the component containing 2 co-formulants with acute inhalation classification is determined in MSDS, therefore there is no need to use for calculation the particular compounds, which are not at significant concentrations. Ultimately, these particular compounds have no impact on final result. Taking into account the classification of the co-formulants of the product LEPTOSAR 200 SL the product should not be classified with regards to the acute inhalation toxicity.

Acute inhalation toxicity value (ATE mix) can be estimated according to principles of Regulation 1272/2008. P. 3.1.3.6.1 (additivity formula) as follows:

$$\frac{100}{ATE_{mix}} = \sum_n \frac{C_i}{ATE_i}$$

Where:

C_i – concentration of ingredient I (% w/w or % v/v)
I – the individual ingredient from 1 to n
n – the number of ingredients
ATE_i – Acute Toxicity Estimate of ingredient i.

There are 2 components (co-formulants) in LEPTOSAR 200 SL with acute inhalation classification and the H330 (Cat. 2) or H331 (Acute Tox. 3) statement.
Their concentration in the product is equal to 0.0000005% and 0.000000015%, respectively.

Taking all above into account the ATE_{mix} for the whole formulation is therefore:

The $ATE_{mix} = \frac{100}{\frac{0.0000005}{0.5} + \frac{0.000000015}{3}}$ >>> 20 mg/L

The estimated value ATE_{mix} of acute ~~oral~~ inhalation toxicity for LEPTOSAR 200 SL is far above 20 mg/L and thus. The product should not be classified with regards to acute inhalation toxicity.
No additional studies are required.

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	The classification of the component containing co-formulants classified with hazard statement H314 i H315 is determined in MSDS, therefore there is no need to take into account the particular compounds, which are not at significant concentrations. Ultimately, these particular compounds have no impact on final result. Taking into account the classification of the co-formulants of the product LEPTOSAR 200 SL, the product should not be classified with regards to the skin corrosion/irritation.

A skin irritation potential of LEPTOSAR 200 SL can be estimated according to principles of Regulation 1272/2008 by using additivity approach.

Two components of LEPTOSAR 200 SL are classified with hazard statement H314. However, their summed up concentration in the product is far below 5%. Therefore the product will not be classified as a Skin Corr. Cat. 1.

One component of LEPTOSAR 200 SL is classified with hazard statement H315. Its concentrations in the product alone is far below 10%. In addition the sum of concentrations of the components with H314 statement multiplied by ten and concentration of one component with H315 statement is far below the concentration limit of 10% (as stated in Table 3.2.3 of Regulation 1272/2008).

Assuming all above. The product will not be classified with H314 or H315 statement.
No skin corrosion/irritation study is necessary.

A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	The classification of the component containing 2 co-formulants classified with hazard statement H318 is determined in MSDS, therefore there is no need to take into account the particular compounds, which are not at significant concentrations. Ultimately, these particular compounds have no impact on final result.

	Taking into account the classification and concentrations of the co-formulants of the product LEPTOSAR 200 SL (one compound classified with hazard statement H319 at the concentration above the limit of 10%), the product should be classified as eye irritant with the H319 statement.

An eye irritation potential of LEPTOSAR 200 SL can be estimated according to principles of Regulation 1272/2008 by using additivity approach.

Two components of LEPTOSAR 200 SL are classified with hazard statement H318. Nevertheless as their summed up concentration in the product is far below 3%. Therefore the product will not be classified as Eye Dam. Cat. 1.

One component of LEPTOSAR 200 SL is classified with hazard statement H319. Its concentrations in the product equals 20.26%. Since it is above the limit concentration of 10% (as stated in Table 3.2.3 of Regulation 1272/2008) the products should be classified as irritative to eyes with the ~~H315~~ H319 statement.

No ~~skin~~ eye ~~corrosion/~~irritation study is necessary.

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	The classification of the component containing 2 co-formulants classified as the skin sensitizer is determined in MSDS, therefore there is no need to take into account the particular compounds, which are not at significant concentrations. Ultimately, these particular compounds have no impact on final result. Taking into account the classification and concentrations of the co-formulants of the product LEPTOSAR 200 SL (one compound classified with hazard statement H317 at the concentration above the limit of 1%), the product should be classified as skin sensitizer with the H317 statement.

A skin or respiratory sensitising potential of LEPTOSAR 200 SL can be estimated according to principles of Regulation 1272/2008 which indicate that if at least one ingredient has been classified as a respiratory or skin sensitiser and is present at or above the appropriate generic concentration limit,~~.~~ ~~T~~the mixture shall be classified as a respiratory or skin sensitiser.

~~One component of LEPTOSAR 200 SL is classified as a respiratory sensitizer. However its concentration in the product is far below the trigger value of 20% and thus, LEPTOSAR 200 SL will not have such classification.~~

Regarding the skin sensitization there are three components classified as the skin sensitizers. In case of two of them their concentrations in the product (0.00000005 and 0.000000015%) are below their specific concentration limit of 0.0015%. The concentration of the third ingredient with H317 Cat. 1B classification (72.18%) is above the general CLP concentration limit of 1%. Taking the last into account LEPTOSAR 200 SL should be classified as the skin sensitizer with H317 Cat. 1 B statement.

No further testing is necessary.

A 2.8 Supplementary studies for combinations of plant protection products (KCP 7.1.7)

Not relevant.

A 2.9 Data on co-formulants (KCP 7.4)

A 2.9.1 Material safety data sheet for each co-formulant

Information regarding material safety data sheets of the co-formulants can be found in the confidential dossier of this submission (Registration Report – Part C).

A 2.9.2 Available toxicological data for each co-formulant

Available toxicological data for each co-formulant can be found in the confidential dossier of this submission (Registration Report – Part C).

A 2.10 Studies on dermal absorption (KCP 7.3)

No study on dermal absorption has been submitted.

A 2.11 Other/Special Studies

None.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for acetamiprid

Table A 1: Input parameters considered for the estimation of operator exposure – EFSA Calculator – use in oilseed rape, mustard, turnip rape

Substance name	Acetamiprid	
Product name	LEPTOSAR 200 SL	
Reference value non acutely toxic active substance (RVNAS)	0,025	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Oilseeds	
Substance properties		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	200	L/ha
Maximum application rate of active substance	0,06	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10,00%	
Dermal absorption of in-use dilution	50,00%	
Oral absorption of active substance	100,00%	
Inhalation absorption of active substance	100,00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Buffer strip	2-3	m
Number of applications	1	
Interval between multiple applications	365	days
Season (upward spraying orchards only)	not relevant	

Table A 2: **Estimation of long-term operator exposure towards active substance according to EFSA guidance – EFSA Calculator – use in oilseed rape, mustard, turnip rape potential exposure and workwear considered**

Application rate of active substance	0,06 kg a.s./ha	*i_AppRate*
Assumed area treated	50 ha/day	*d_AreaTreated*
Amount of active substance applied	3 kg a.s./day	*i_AmountAS*
Dermal absorption of the product	10,00%	*i_AbsorpProduct*
Dermal absorption of in-use dilution	50,00%	*i_AbsorpInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

Mixing and loading

Exposure values	µg exposure/day mixed and loaded		Reference	Comment
	75th centile	95th centile		
Hands	11315	41864	AOEM	
Body	7722	99105	AOEM	
Head	156	854	AOEM	
Protected hands (gloves)	70	594	AOEM	
Protected body (workwear or protective garment and sturdy footwear)	63	439	AOEM	
Protected head (hood and face shield)	2	48	AOEM	
Inhalation	5	29	AOEM	
Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	No			
Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
Head and respiratory PPE	None		1	1
Water soluble bag	No		1	

Application

Exposure values	µg exposure/day applied		Reference	Comment
	75th centile	95th centile		
Hands	445	5124	AOEM	
Body	249	1283	AOEM	
Head	12	35	AOEM	
Protected hands (gloves)	77	3789	AOEM	
Protected body (workwear or protective garment and sturdy footwear)	7	17	AOEM	
Inhalation	2	5	AOEM	
Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	No			
Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
Head and respiratory PPE	None		1	1
Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	2,2789475	1,3920847	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0379825	0,0232014	
% of RVNAS	151,93%	92,81%	

Table A 14: Input parameters considered for the estimation of operator exposure – EFSA Calculator – use in cereals (wheat, rye, triticale)

Substance name	acetamiprid	
Product name	LEPTOSAR 200 SL	
Reference value non acutely toxic active substance (RVNAS)	0,025	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Cereals	
Substance properties		
Formulation type	oluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	200	L/ha
Maximum application rate of active substance	0,04	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10,00%	
Dermal absorption of in-use dilution	50,00%	
Oral absorption of active substance	100,00%	
Inhalation absorption of active substance	100,00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Buffer strip	2-3	m
Number of applications	1	
Interval between multiple applications	365	days
Season (upward spraying orchards only)	not relevant	

Application rate of active substance	0,04 kg a.s./ha		*i_AppRate*
Assumed area treated	50 ha/day		*d_AreaTreated*
Amount of active substance applied	2 kg a.s./day		*i_AmountAS*
Dermal absorption of the product	10,00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50,00%		*i_AbsorpInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Season	not relevant		

Mixing and loading

Exposure values	µg exposure/day mixed and loaded		Reference	Comment
	75th centile	95th centile		
Hands	8281	30530	AOEM	
Body	5807	88092	AOEM	
Head	104	569	AOEM	
Protected hands (gloves)	54	396	AOEM	
Protected body (workwear or protective garment and sturdy footwear)	44	293	AOEM	
Protected head (hood and face shield)	2	32	AOEM	
Inhalation	5	29	AOEM	
Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	No			
Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
Head and respiratory PPE	None		1	1
Water soluble bag	No		1	

Application

Exposure values	µg exposure/day applied		Reference	Comment
	75th centile	95th centile		
Hands	297	3807	AOEM	
Body	166	855	AOEM	
Head	8	24	AOEM	
Protected hands (gloves)	62	3614	AOEM	
Protected body (workwear or protective garment and sturdy footwear)	5	11	AOEM	
Inhalation	1	4	AOEM	
Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	No			
Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
Head and respiratory PPE	None		1	1
Closed cab	No		vehicle mounted upward spraying only	

Table A 15: Estimation of long-term operator exposure towards active substance according to EFSA guidance – EFSA Calculator – use in cereals (wheat, rye, triticale) potential exposure and workwear considered

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1,6603791	1,0034401	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0276730	0,0167240	
% of RVNAS	110,69%	66,90%	

Table A 16: Input parameters considered for the estimation of operator exposure – EFSA Calculator – use in maize, sorghum, millet

Substance name	acetamiprid	
Product name	LEPTOSAR 200 SL	
Reference value non acutely toxic active substance (RVNAS)	0,025	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Cereals	
Substance properties		
Formulation type	oluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	300	L/ha
Maximum application rate of active substance	0,06	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10,00%	
Dermal absorption of in-use dilution	50,00%	
Oral absorption of active substance	100,00%	
Inhalation absorption of active substance	100,00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Buffer strip	2-3	m
Number of applications	1	
Interval between multiple applications	365	days
Season (upward spraying orchards only)	not relevant	

Application rate of active substance	0,06	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	3	kg a.s./day	*i_AmountAS*
Dermal absorption of the product	10,00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50,00%		*i_AbsorpInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Season	not relevant		

Dustproof soluble concentrates, emulsifiable concentrates or dispersible concentrates (wb/dispersion)

Mixing and loading

Exposure values	µg exposure/day mixed and loaded		Reference	Comment
	75th centile	95th centile		
Hands	11315	41864	AOEM	
Body	7722	99105	AOEM	
Head	156	854	AOEM	
Protected hands (gloves)	70	594	AOEM	
Protected body (workwear or protective garment and sturdy footwear)	63	439	AOEM	
Protected head (hood and face shield)	2	48	AOEM	
Inhalation	5	29	AOEM	
Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	Yes		cl. in AOEM model	
Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
Head and respiratory PPE	None		1	1
Water soluble bag	No		1	

Application

Exposure values	µg exposure/day applied		Reference	Comment
	75th centile	95th centile		
Hands	445	5124	AOEM	
Body	249	1283	AOEM	
Head	12	35	AOEM	
Protected hands (gloves)	77	3789	AOEM	
Protected body (workwear or protective garment and sturdy footwear)	7	17	AOEM	
Inhalation	2	5	AOEM	
Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	No			
Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
Head and respiratory PPE	None		1	1
Closed cab	No		vehicle mounted upward spraying only	

Table A 17: Estimation of long-term operator exposure towards active substance according to EFSA guidance – EFSA Calculator – use in maize, sorghum, millet potential exposure and workwear considered

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	2,2789475	1,3920847	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0379825	0,0232014	
% of RVNAS	151,93%	92,81%	

Table A 18: Input parameters considered for the estimation of operator exposure – EFSA Calculator – use in soybean and pumpkin

Substance name	acetamiprid	
Product name	LEPTOSAR 200 SL	
Reference value non acutely toxic active substance (RVNAS)	0,025	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Legume vegetables/ Brassica vegetables	
Substance properties		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
inimum volume water for application (liquids)	200	L/h a
Maximum application rate of active substance	0,06	kg a.s. /ha
50% Dissipation Time DT50	30	da ys
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10,00%	
Dermal absorption of in-use dilution	50,00%	
Oral absorption of active substance	100,00%	
Inhalation absorption of active substance	100,00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Buffer strip	2-3	m
Number of applications	1	
Interval between multiple applications	365	da ys

Season (upward spraying orchards only)	not relevant

Application rate of active substance	0,06	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	3	kg a.s./day	*i_AmountAS*
Dermal absorption of the product	10,00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50,00%		*i_AbsorpInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Season	not relevant		

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	11315	41864	AOEM	
	Body	7722	99105	AOEM	
	Head	156	854	AOEM	
	Protected hands (gloves)	70	594	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	63	439	AOEM	
	Protected head (hood and face shield)	2	48	AOEM	
	Inhalation	5	29	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	445	5124	AOEM	
	Body	249	1283	AOEM	
	Head	12	35	AOEM	
	Protected hands (gloves)	77	3789	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	7	17	AOEM	
	Inhalation	2	5	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

Table A 19: Estimation of long-term operator exposure towards active substance according to EFSA guidance – EFSA Calculator – use in soybean and pumpkin potential exposure and workwear considered

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	2,2789475	1,3920847	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0379825	0,0232014	
% of RVNAS	151,93%	92,81%	

Table A 20: Input parameters considered for the estimation of operator exposure – EFSA Calculator – use in apple, pear, quince, medlar (Pome fruits), cherry, peach, nectarine, apricot, plum (stone fruits) and hazelnut, walnut (tree nuts)

Substance name	acetamiprid	
Product name	LEPTOSAR 200 SL	
Reference value non acutely toxic active substance (RVNAS)	0,025	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Pome fruits/Stone fruits/Tree nuts	
Substance properties		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
inimum volume water for application (liquids)	200	L/ha
Maximum application rate of active substance	0,025	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10,00%	
Dermal absorption of in-use dilution	50,00%	
Oral absorption of active substance	100,00%	
Inhalation absorption of active substance	100,00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Buffer strip	5	m
Number of applications	2	
Interval between multiple applications	7	days
Season (upward spraying orchards only)	not relevant	

Application rate of active substance	0,025	kg a.s./ha	*i_AppRate*
Assumed area treated	10	ha/day	*d_AreaTreated*
Amount of active substance applied	0,25	kg a.s./day	*i_AmountAS*
Dermal absorption of the product	10,00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50,00%		*i_AbsorpInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Upward spraying		
Application equipment	Vehicle-mounted		
Season	not relevant		

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	1671	6047	AOEM	
	Body	1346	48147	AOEM	
	Head	13	71	AOEM	
	Protected hands (gloves)	14	50	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	7	37	AOEM	
	Protected head (hood and face shield)	0	4	AOEM	
	Inhalation	2	28	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	738	1559	AOEM	No data available for a drift reduction scenario
	Body	2203	12854	AOEM	
	Head	290	1777	AOEM	
	Protected hands (gloves)	9	230	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	29	56	AOEM	
	Inhalation	29	21	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

Table A 21: **Estimation of long-term operator exposure towards active substance according to EFSA guidance – EFSA Calculator – use in in apple, pear, quince, medlar (Pome fruits), cherry, peach, nectarine, apricot, plum (stone fruits) and hazelnut, walnut (tree nuts) potential exposure and workwear considered**

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1,9498245	0,7288031	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0324971	0,0121467	
% of RVNAS	129,99%	48,59%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	13,5699410	2,3599873	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,2261657	0,0393331	
% of RVAAS	#DIV/0!	#DIV/0!	

Table A 22: **Input parameters considered for the estimation of operator exposure – EFSA Calculator – use in forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees plantations (Pome fruits)**

Substance name	acetamiprid	
Product name	LEPTOSAR 200 SL	
Reference value non acutely toxic active substance (RVNAS)	0,025	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Pome fruit	
Substance properties		
Formulation type	oluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	200	L/ha
Maximum application rate of active substance	0,05	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10,00%	
Dermal absorption of in-use dilution	50,00%	
Oral absorption of active substance	100,00%	
Inhalation absorption of active substance	100,00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Buffer strip	5	m
Number of applications	1	
Interval between multiple applications	365	days
Season (upward spraying orchards only)	not relevant	

Application rate of active substance	0,05 kg a.s./ha	*i_AppRate*
Assumed area treated	10 ha/day	*d_AreaTreated*
Amount of active substance applied	0,5 kg a.s./day	*i_AmountAS*
Dermal absorption of the product	10,00%	*i_AbsorpProduct*
Dermal absorption of in-use dilution	50,00%	*i_AbsorpInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	2849	10374	AOEM	
	Body	2191	58887	AOEM	
	Head	26	142	AOEM	
	Protected hands (gloves)	22	99	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	13	73	AOEM	
	Protected head (hood and face shield)	0	8	AOEM	
	Inhalation	3	28	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	1365	3118	AOEM	No data available for a drift reduction scenario
	Body	4406	25708	AOEM	
	Head	579	3554	AOEM	
	Protected hands (gloves)	18	460	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	57	112	AOEM	
	Inhalation	43	41	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

Table A 23: Estimation of long-term operator exposure towards active substance according to EFSA guidance – EFSA Calculator – use in forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees plantations (Pome fruits)

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	3,7275002	1,3354583	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0621250	0,0222576	
% of RVNAS	248,50%	89,03%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	23,1999585	4,5206460	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,3866660	0,0753441	
% of RVAAS	#DIV/0!	#DIV/0!	

Table A 24: **Input and output parameters considered for the estimation of operator exposure – ~~EFSA Calculator~~ Dutch Model– use in green house (tomato, aubergine, paprika)**

OPERATOR EXPOSURE			DUTCH GREENHOUSE MODEL	
form	LEPTOSAR 200 SL		Application including mixing and loading	
a.s.	acetamiprid			
Parameter		Value	Unit	References, comments
MANUAL SPRAYING in greenhouses				
AR	Application rate	0,06	kg a.s./ha	summary of intended uses
A	Area treated	1	ha/day	Dutch model
Inhalation Exposure				without PPE
SV	Surrogate Exposure Value	1	mg a.s./kg a.s.	For dusting see note* (Dutch model)
Inhalation Exposure (without PPE)		0,06	mg a.s./day	IE = SV x AR x A
Inhalation Exposure (with PPE)				with PPE
	PPE-factor	1		Non-powered mask filtertype 2 (most conservative): 10; more advanced RPE see note** (Dutch model)
Inhalation Exposure (with PPE)		0,06	mg a.s./day	IE(PPE) = (1/PPE factor) x IE
Dermal Exposure				without PPE
SV	Surrogate Exposure Value	200	mg a.s./kg a.s.	For dusting see note* (Dutch model)
Dermal Exposure		12	mg a.s./day	DE = SV x AR x A
Dermal Exposure (with PPE)				with PPE
	PPE-factor	10		Gloves + coverall: 10 (Dutch model)
Dermal Exposure (with PPE)		1,2	mg a.s./day	DE(PPE) = (1/PPE-factor) x DE
Internal exposure				
IA	Inhalation Absorption	100	%	
DA	Dermal Absorption	50	%	
	AOEL	1,5	mg a.s./day	based on 70 kg bw
		Without PPE	With PPE	
	Internal exposure	[mg a.s. /day]	[mg a.s. /day]	
	Inhalation	0,0600	0,0600	IE(int) = IE x (IA/100)
	Dermal	6,0000	0,6000	DE(int) = DE x (DA/100)
	Total	6,0600	0,6600	sum
	%AOEL			
	Inhalation	4	4	%AOEL = 100 x IE(int) / AOEL
	Dermal	400	40	%AOEL = 100 x DE(int) / AOEL
	Total	404	44	sum
*	NOTE: The above mentioned model is for spraying in greenhouses. For dusting of cornelations the surrogate values should be changed. Inhalation should be 20 mg/kg instead of 1, and dermal should be 300 mg/kg instead of 200.			
**	Note: Only for (pelforming) gaseous preparations and soil fumigation preparations: powered full-face filtering devices with filtertype 2 (factor 20), powered full-face filtering devices with filtertype 3 (factor 40)			

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for acetamiprid

Table A 3: **Input parameters considered for the estimation of worker exposure – EFSA calculator – use in oilseed rape, mustard, turnip rape**

Crop type	Oilseeds		
Indoor or outdoor	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Inspection, irrigation		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	0,06	kg a.s./ha	*i_AppRate*
Number of applications	1		*i_AppNo*
Interval between multiple applications	365	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1,0		*d_MAF*
Dermal absorption of the product	10,00%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	50,00%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,18	µg a.s./cm^2	*d_DFR*
Working hours	2	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	12500	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	1400	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm^2/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcSort*

Table A 26: Estimation of long-term worker exposure towards active substance according to EFSA guidance – use in oilseed rape, mustard, turnip rape

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	2,2500000	0,2520000	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0375000	0,0042000		
% of RVNAS	150,00%	16,80%		

2. Details

	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
Dermal - Potential	2,2500000	0,0375000	*d_DermTcUCV*d_WorkHr*i_DFR*i_MAF/1000*i_AbsorpInuse*	
Dermal - Work wear - arms, body and legs covered	0,2520000	0,0042000	*d_DermTcCV1*d_WorkHr*d_DFR*d_MAF/1000*i_AbsorpInuse*	
Dermal - Working wear and gloves	no TC available for this assessment		*d_DermTcCV2*d_WorkHr*d_DFR*d_MAF/1000*i_AbsorpInuse*	
Inhalation				Na for outdoor activities

Table A 27: Input parameters considered for the estimation of worker exposure – EFSA calculator – use in cereals (wheat, rye, triticale)

Crop type	Cereals		
Indoor or outdoor	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Inspection, irrigation		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	0,04	kg a.s./ha	*i_AppRate*
Number of applications	1		*i_AppNo*
Interval between multiple applications	365	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1,0		*d_MAF*
Dermal absorption of the product	10,00%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	50,00%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,12	µg a.s./cm^2	*d_DFR*
Working hours	2	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	12500	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	1400	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm^2/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcSort*

Table A 28: Estimation of long-term worker exposure towards active substance according to EFSA guidance – use in cereals (wheat, rye, triticale)

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	1,5000000	0,1680000	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0250000	0,0028000		
% of RVNAS	100,00%	11,20%		

2. Details

	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
Dermal - Potential	1,5000000	0,0250000	*d_DermTcUCV*d_WorkHr*i_DFR*i_MAF/1000*i_AbsorpInuse*	
Dermal - Work wear - arms, body and legs covered	0,1680000	0,0028000	*d_DermTcCV1*d_WorkHr*d_DFR*d_MAF/1000*i_AbsorpInuse*	
Dermal - Working wear and gloves	no TC available for this assessment		*d_DermTcCV2*d_WorkHr*d_DFR*d_MAF/1000*i_AbsorpInuse*	
Inhalation				Na for outdoor activities

Table A 29: Input parameters considered for the estimation of worker exposure – EFSA calculator – use in maize, sorghum, millet

Crop type	Cereals		
Indoor or outdoor	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Inspection, irrigation		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	0,06	kg a.s./ha	*i_AppRate*
Number of applications	1		*i_AppNo*
Interval between multiple applications	365	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1,0		*d_MAF*
Dermal absorption of the product	10,00%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	50,00%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,18	µg a.s./cm^2	*d_DFR*
Working hours	2	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	12500	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	1400	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm^2/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcSort*

Table A 30: Estimation of long-term worker exposure towards active substance according to EFSA guidance – use in maize, sorghum, millet

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	2,2500000	0,2520000	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0375000	0,0042000		
% of RVNAS	150,00%	16,80%		

2. Details

	Systemic exposure [mg a.s. /day]	[mg a.s./kg bw/day]	Formula	Comments
Dermal - Potential	2,2500000	0,0375000	*d_DermTcUCV*d_WorkHr*i_DFR*i_MAF/1000*i_AbsorpInuse*	
Dermal - Work wear - arms, body and legs covered	0,2520000	0,0042000	*d_DermTcCV1*d_WorkHr*d_DFR*d_MAF/1000*i_AbsorpInuse*	
Dermal - Working wear and gloves	no TC available for this assessment		*d_DermTcCV2*d_WorkHr*d_DFR*d_MAF/1000*i_AbsorpInuse*	
Inhalation				Na for outdoor activities

Table A 31: Input parameters considered for the estimation of worker exposure – EFSA calculator – use in soybean and pumpkin

Crop type	Legume vegetables/ Brassica vegetables		
Indoor or outdoor	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Reaching, picking		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	0,06	kg a.s./ha	*i_AppRate*
Number of applications	1		*i_AppNo*
Interval between multiple applications	365	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1,0		*d_MAF*

Dermal absorption of the product	10,00%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	50,00%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,18	µg a.s./cm^2	*d_DFR*
Working hours	8	hr	*d_WorkHr*
Dermal transfer coefficient – Total potential exposure	5800	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient – arms, body and legs covered	2500	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient – hands, arms, body and legs covered	580	cm^2/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcSort*

Table A 32: Estimation of long-term worker exposure towards active substance according to EFSA guidance – use in soybean and pumpkin

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	4,1760000	1,8000000	0,4176000	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0696000	0,0300000	0,0069600	
% of RVNAS	278,40%	120,00%	27,84%	

2. Details

	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
Dermal - Potential	4,1760000	0,0696000	*d_DermTcUCV*d_WorkHr*i_DFR*i_MAF/1000*i_AbsorpInuse*	
Dermal - Work wear - arms, body and legs covered	1,8000000	0,0300000	*d_DermTcCV1*d_WorkHr*d_DFR*d_MAF/1000*i_AbsorpInuse*	
Dermal - Working wear and gloves	0,4176000	0,0069600	*d_DermTcCV2*d_WorkHr*d_DFR*d_MAF/1000*i_AbsorpInuse*	
Inhalation				Na for outdoor activities

Table A 33: Input parameters considered for the estimation of worker exposure – EFSA calculator – use in apple, pear, quince, medlar (Pome fruits), cherry, peach, nectarine, apricot, plum (stone fruits) and hazelnut, walnut (tree nut)

Crop type	Pome fruits/ Stone fruits/Tree nuts		
Indoor or outdoor	Outdoor		
Application method	Upward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Searching, reaching, picking		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	0,025	kg a.s./ha	*i_AppRate*
Number of applications	2		*i_AppNo*
Interval between multiple applications	7	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1,9		*d_MAF*
Dermal absorption of the product	10,00%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	50,00%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,075	µg a.s./cm^2	*d_DFR*
Working hours	8	hr	*d_WorkHr*
Dermal transfer coefficient – Total potential exposure	22500	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient – arms, body and	4500	cm^2/hr	*d_DermTcCV1*

legs covered			
Dermal transfer coefficient – hands, arms, body and legs covered	2250	cm^2/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcSort*

Table A 34: Estimation of long-term worker exposure towards active substance according to EFSA guidance – use in apple, pear, quince, medlar (Pome fruits), cherry, peach, nectarine, apricot, plum (stone fruits) and hazelnut, walnut (tree nut)

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	12,4920033	2,4984007	1,2492003	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,2082001	0,0416400	0,0208200	
% of RVNAS	832,80%	166,56%	83,28%	

Table A 4: Input parameters considered for the estimation of worker exposure – EFSA calculator – use in forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees plantations (Pome fruits)

Crop type	Pome fruit		
Indoor or outdoor	Outdoor		
Application method	Upward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Searching, reaching, picking		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	0,05	kg a.s./ha	*i_AppRate*
Number of applications	1		*i_AppNo*
Interval between multiple applications	365	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1,0		*d_MAF*
Dermal absorption of the product	10,00%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	50,00%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,15	µg a.s./cm^2	*d_DFR*
Working hours	8	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	22500	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	4500	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	2250	cm^2/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcSort*

Table A 36: **Estimation of long-term worker exposure towards active substance according to EFSA guidance – use in Forest and ornamental nurseries plants, restockings, afforestat)ions and forest trees' seed plantations; Christmas trees plantations (Pome fruits)**

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	13,5000000	2,7000000	1,3500000	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,2250000	0,0450000	0,0225000	
% of RVNAS	900,00%	180,00%	90,00%	

Table A 37: **Input parameters considered for the estimation of worker exposure – EFSA calculator – use in green house (tomato, aubergine paprika)**

Substance name	acetamiprid	
Product name	LEPTOSAR 200 SL	
Reference value non acutely toxic active substance (RVNAS)	0,025	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)		mg/kg bw/day
Crop type	Fruiting vegetables	
Substance properties		
Formulation type	oluble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	300	L/ha
Maximum application rate of active substance	0,06	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	10,00%	
Dermal absorption of in-use dilution	50,00%	
Oral absorption of active substance	100,00%	
Inhalation absorption of active substance	100,00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Indoor	
Application method	Spray application	
Application equipment	Manual	
Buffer strip	2-3	m
Number of applications	1	
Interval between multiple applications	365	days
Season (upward spraying orchards only)	not relevant	

Table A 38: **Estimation of long-term worker exposure towards active substance according to EFSA guidance – use in green house (tomato, aubergine paprika)**

Crop type	Fruiting vegetables		
Indoor or outdoor	Indoor		
Application method	Spray application		
Application equipment	Manual		
Worker's task	Reaching, picking		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	0,06	kg a.s./ha	*i_AppRate*
Number of applications	1		*i_AppNo*
Interval between multiple applications	365	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1,0		*d_MAF*
Dermal absorption of the product	10,00%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	50,00%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,18	µg a.s./cm^2	*d_DFR*
Working hours	8	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	5800	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	2500	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	580	cm^2/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcSort*

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	4,1760000	1,8000000	0,4176000	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0696000	0,0300000	0,0069600	
% of RVNAS	278,40%	120,00%	27,84%	

Table A 39: Input parameters and estimation of long-term worker exposure – EUROPOEM II calculator – use in oilseed rape, mustard, turnip rape; potential exposure

WORKER EXPOSURE			EUROPOEM II MODEL	
form	LEPTOSAR 200 SL		Re-entry in the field	
a.s.	acetamiprid			
Parameter		**Value**	**Unit**	**References, comments**
Re-entry activities in the field				
AR	Application rate	0,06	kg a.s./ha	summary of intended uses
Worker				
Duration				
T		2	hours / day	default: 6 h (Europoem II)
Inhalation Exposure				without PPE
	no model available	-		
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	1,25	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure		**4,5**	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure				
DA	Dermal Absorption	50	%	
	PPE-factor dermal	5		gloves*
	AOEL	1,5	mg a.s./ day	based on 70 kg bw
		Without PPE	**With PPE**	
	Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	2,250	0,450	DE(int) = DE x (DA/100)
	Total	**2,250**	**0,450**	**sum**
	% AOEL			
	Inhalation	-	-	no model available
	Dermal	150	30	%AOEL = 100 x DE(int) / AOEL
	Total	**150**	**30**	**sum**

* It is assumed in the used TC values, that body exposure is already reduced by (protective) clothing. The use of gloves will result in an extra reduction factor of 5.

Table A 40: Input parameters and estimation of long-term worker exposure – EUROPOEM II calculator – use in oilseed rapes, mustard, turnip rape; workwear (and gloves) considered

WORKER EXPOSURE — EUROPOEM II MODEL

form	LEPTOSAR 200 SL		Re-entry in the field	
a.s.	acetamiprid			
Parameter		**Value**	**Unit**	**References, comments**
Re-entry activities in the field				
AR	Application rate	0,06	kg a.s./ha	summary of intended uses
Worker				
Duration				
T		2	hours / day	default: 6 h (Europoem II)
Inhalation Exposure				without PPE
	no model available	-		
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	0,14	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure		**0,504**	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure				
DA	Dermal Absorption	50	%	
	PPE-factor dermal	5		gloves*
	AOEL	1,5	mg a.s./ day	based on 70 kg bw
		Without PPE	**With PPE**	
	Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	0,252	0,050	DE(int) = DE x (DA/100)
	Total	**0,252**	**0,050**	**sum**
	% AOEL			
	Inhalation	-	-	no model available
	Dermal	17	3	%AOEL = 100 x DE(int) / AOEL
	Total	**17**	**3**	**sum**

* It is assumed in the used TC values, that body exposure is already reduced by (protective) clothing. The use of gloves will result in an extra reduction factor of 5.

Table A 41: Input parameters and estimation of long-term worker exposure – EUROPOEM II calculator – use in cereals (wheat, rye, triticale); potential exposure

WORKER EXPOSURE			EUROPOEM II MODEL	
form	LEPTOSAR 200 SL		Re-entry in the field	
a.s.	acetamiprid			
Parameter		**Value**	**Unit**	**References, comments**
Re-entry activities in the field				
AR	Application rate	0,04	kg a.s./ha	summary of intended uses
Worker				
Duration				
T		2	hours / day	default: 6 h (Europoem II)
Inhalation Exposure				without PPE
	no model available	-		
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	1,25	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure		3	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure				
DA	Dermal Absorption	50	%	
	PPE-factor dermal	5		gloves*
	AOEL	1,5	mg a.s./ day	based on 70 kg bw
		Without PPE	**With PPE**	
	Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	1,500	0,300	DE(int) = DE x (DA/100)
	Total	**1,500**	**0,300**	**sum**
	% AOEL			
	Inhalation	-	-	no model available
	Dermal	100	20	%AOEL = 100 x DE(int) / AOEL
	Total	**100**	**20**	**sum**

* It is assumed in the used TC values, that body exposure is already reduced by (protective) clothing. The use of gloves will result in an extra reduction factor of 5.

Table A 42: Input parameters and estimation of long-term worker exposure – EUROPOEM II calculator – use in cereals (wheat, rye, triticale); workwear (and gloves) considered

WORKER EXPOSURE			EUROPOEM II MODEL	
form	LEPTOSAR 200 SL		Re-entry in the field	
a.s.	acetamiprid			
Parameter		**Value**	**Unit**	**References, comments**
Re-entry activities in the field				
AR	Application rate	0,04	kg a.s./ha	summary of intended uses
Worker				
Duration				
T		2	hours / day	default: 6 h (Europoem II)
Inhalation Exposure				without PPE
	no model available	-		
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	0,14	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure		**0,336**	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure				
DA	Dermal Absorption	50	%	
	PPE-factor dermal	5		gloves*
	AOEL	1,5	mg a.s./ day	based on 70 kg bw
		Without PPE	**With PPE**	
	Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	0,168	0,034	DE(int) = DE x (DA/100)
	Total	**0,168**	**0,034**	**sum**
	% AOEL			
	Inhalation	-	-	no model available
	Dermal	11	2	%AOEL = 100 x DE(int) / AOEL
	Total	**11**	**2**	**sum**
*	It is assumed in the used TC values, that body exposure is already reduced by (protective) clothing. The use of gloves will result in an extra reduction factor of 5.			

Table A 43: Input parameters and estimation of long-term worker exposure – EUROPOEM II calculator – use in maize, sorghum, millet; potential exposure

WORKER EXPOSURE			EUROPOEM II MODEL	
form	LEPTOSAR 200 SL		Re-entry in the field	
a.s.	acetamiprid			
Parameter		**Value**	**Unit**	**References, comments**
Re-entry activities in the field				
AR	Application rate	0,06	kg a.s./ha	summary of intended uses
Worker				
Duration				
T		2	hours / day	default: 6 h (Europoem II)
Inhalation Exposure				without PPE
	no model available	-		
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	1,25	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure		4,5	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure				
DA	Dermal Absorption	50	%	
	PPE-factor dermal	5		gloves*
	AOEL	1,5	mg a.s./ day	based on 70 kg bw
		Without PPE	**With PPE**	
	Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	2,250	0,450	DE(int) = DE x (DA/100)
	Total	**2,250**	**0,450**	**sum**
	% AOEL			
	Inhalation	-	-	no model available
	Dermal	150	30	%AOEL = 100 x DE(int) / AOEL
	Total	**150**	**30**	**sum**
*	It is assumed in the used TC values, that body exposure is already reduced by (protective) clothing. The use of gloves will result in an extra reduction factor of 5.			

Table A 44: Input parameters and estimation of long-term worker exposure – EUROPOEM II calculator – use in maize, sorghum, millet; workwear (and gloves) considered

WORKER EXPOSURE			EUROPOEM II MODEL	
form	LEPTOSAR 200 SL		Re-entry in the field	
a.s.	acetamiprid			
Parameter		**Value**	**Unit**	**References, comments**
Re-entry activities in the field				
AR	Application rate	0,06	kg a.s./ha	summary of intended uses
Worker				
Duration				
T		2	hours / day	default: 6 h (Europoem II)
Inhalation Exposure				without PPE
	no model available	-		
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	0,14	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure		**0,504**	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure				
DA	Dermal Absorption	50	%	
	PPE-factor dermal	5		gloves*
	AOEL	1,5	mg a.s./ day	based on 70 kg bw
		Without PPE	**With PPE**	
	Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	0,252	0,050	DE(int) = DE x (DA/100)
	Total	**0,252**	**0,050**	**sum**
	% AOEL			
	Inhalation	-	-	no model available
	Dermal	17	3	%AOEL = 100 x DE(int) / AOEL
	Total	**17**	**3**	**sum**

* It is assumed in the used TC values, that body exposure is already reduced by (protective) clothing. The use of gloves will result in an extra reduction factor of 5.

Table A 45: Input parameters and estimation of long-term worker exposure – EUROPOEM II calculator – use in soybean and pumpkin; potential exposure

WORKER EXPOSURE			EUROPOEM II MODEL	
form	LEPTOSAR 200 SL		Re-entry in the field	
a.s.	acetamiprid			
Parameter		**Value**	**Unit**	**References, comments**
Re-entry activities in the field				
AR	Application rate	0,06	kg a.s./ha	summary of intended uses
Worker				
Duration				
T		8	hours / day	default: 6 h (Europoem II)
Inhalation Exposure				without PPE
	no model available	-		
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	0,58	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure		**8,352**	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure				
DA	Dermal Absorption	50	%	
	PPE-factor dermal	5		gloves*
	AOEL	1,5	mg a.s./ day	based on 70 kg bw
		Without PPE	**With PPE**	
	Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	4,176	0,835	DE(int) = DE x (DA/100)
	Total	**4,176**	**0,835**	**sum**
	% AOEL			
	Inhalation	-	-	no model available
	Dermal	278	56	%AOEL = 100 x DE(int) / AOEL
	Total	**278**	**56**	**sum**
*	It is assumed in the used TC values, that body exposure is already reduced by (protective) clothing. The use of gloves will result in an extra reduction factor of 5.			

Table A 46: Input parameters and estimation of long-term worker exposure – EUROPOEM II calculator – use in soybean and pumpkin; workwear and gloves

WORKER EXPOSURE			EUROPOEM II MODEL	
form	LEPTOSAR 200 SL		Re-entry in the field	
a.s.	acetamiprid			
Parameter		**Value**	**Unit**	**References, comments**
Re-entry activities in the field				
AR	Application rate	0,06	kg a.s./ha	summary of intended uses
Worker				
Duration				
T		8	hours / day	default: 6 h (Europoem II)
Inhalation Exposure				without PPE
	no model available	-		
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	0,25	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure		3,6	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure				
DA	Dermal Absorption	50	%	
	PPE-factor dermal	5		gloves*
	AOEL	1,5	mg a.s./ day	based on 70 kg bw
		Without PPE	**With PPE**	
	Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	1,800	0,360	DE(int) = DE x (DA/100)
	Total	**1,800**	**0,360**	**sum**
	% AOEL			
	Inhalation	-	-	no model available
	Dermal	120	24	%AOEL = 100 x DE(int) / AOEL
	Total	**120**	**24**	**sum**
*	It is assumed in the used TC values, that body exposure is already reduced by (protective) clothing. The use of gloves will result in an extra reduction factor of 5.			

Table A 47: Input parameters and estimation of long-term worker exposure – EUROPOEM II calculator – use in apple, pear, quince, medlar (Pome fruits), cherry, peach, nectarine, apricot, plum (stone fruits) and hazelnut, walnut (tree nut); potential exposure

WORKER EXPOSURE			EUROPOEM II MODEL	
form	LEPTOSAR 200 SL		Re-entry in the field	
a.s.	acetamiprid			
Parameter		**Value**	**Unit**	**References, comments**
Re-entry activities in the field				
AR	Application rate	0,0475	kg a.s./ha	summary of intended uses
Worker				
Duration				
T		8	hours / day	default: 6 h (Europoem II)
Inhalation Exposure				without PPE
	no model available	-		
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	2,25	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure		**25,65**	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure				
DA	Dermal Absorption	50	%	
	PPE-factor dermal	5		gloves*
	AOEL	1,5	mg a.s./ day	based on 70 kg bw
		Without PPE	**With PPE**	
	Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	12,825	2,565	DE(int) = DE x (DA/100)
	Total	**12,825**	**2,565**	**sum**
	% AOEL			
	Inhalation	-	-	no model available
	Dermal	855	171	%AOEL = 100 x DE(int) / AOEL
	Total	**855**	**171**	**sum**
*	It is assumed in the used TC values, that body exposure is already reduced by (protective) clothing. The use of gloves will result in an extra reduction factor of 5.			

Table A 48: **Input parameters and estimation of long-term worker exposure – EUROPOEM II calculator – use in apple, pear, quince, medlar (Pome fruits), cherry, peach, nectarine, apricot, plum (stone fruits) and hazelnut, walnut (tree nut); workwear and gloves**

WORKER EXPOSURE			EUROPOEM II MODEL	
form	LEPTOSAR 200 SL		Re-entry in the field	
a.s.	acetamiprid			
Parameter		**Value**	**Unit**	**References, comments**
Re-entry activities in the field				
AR	Application rate	0,0475	kg a.s./ha	summary of intended uses
Worker				
Duration				
T		8	hours / day	default: 6 h (Europoem II)
Inhalation Exposure				without PPE
	no model available	-		
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	0,45	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure		**5,13**	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure				
DA	Dermal Absorption	50	%	
	PPE-factor dermal	5		gloves*
	AOEL	1,5	mg a.s./ day	based on 70 kg bw
		Without PPE	**With PPE**	
	Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	2,565	0,513	DE(int) = DE x (DA/100)
	Total	**2,565**	**0,513**	**sum**
	% AOEL			
	Inhalation	-	-	no model available
	Dermal	171	34	%AOEL = 100 x DE(int) / AOEL
	Total	**171**	**34**	**sum**

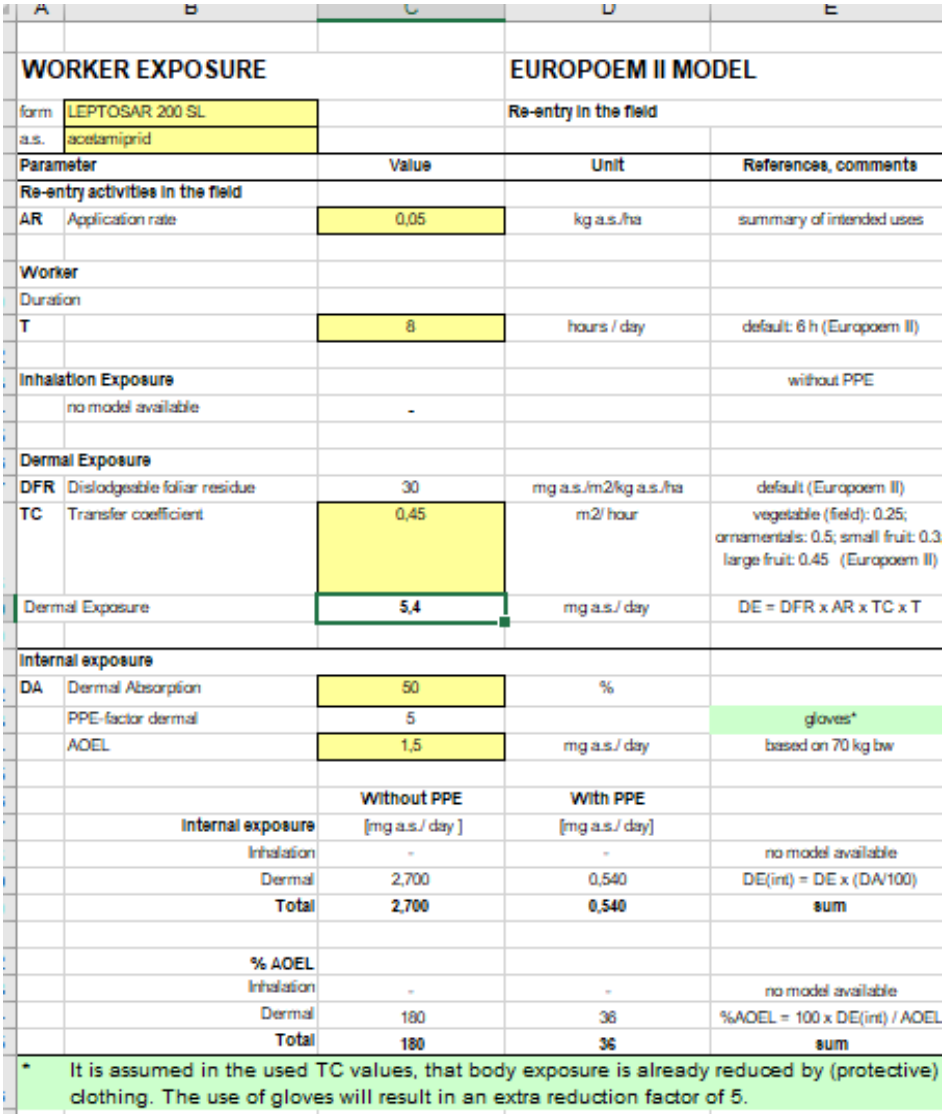
* It is assumed in the used TC values, that body exposure is already reduced by (protective) clothing. The use of gloves will result in an extra reduction factor of 5.

Table A 49: **Input parameters and estimation of long-term worker exposure – EUROPOEM II calculator – use in Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations /Christmas trees plantation (Pome fruits); potential exposure**

WORKER EXPOSURE			EUROPOEM II MODEL	
form	LEPTOSAR 200 SL		Re-entry in the field	
a.s.	acetamiprid			
Parameter		**Value**	**Unit**	**References, comments**
Re-entry activities in the field				
AR	Application rate	0,05	kg a.s./ha	summary of intended uses
Worker				
Duration				
T		8	hours / day	default: 6 h (Europoem II)
Inhalation Exposure				without PPE
	no model available	-		
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	2,25	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure		27	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure				
DA	Dermal Absorption	50	%	
	PPE-factor dermal	5		gloves*
	AOEL	1,5	mg a.s./ day	based on 70 kg bw
		Without PPE	**With PPE**	
	Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	13,500	2,700	DE(int) = DE x (DA/100)
	Total	**13,500**	**2,700**	**sum**
	% AOEL			
	Inhalation	-	-	no model available
	Dermal	900	180	%AOEL = 100 x DE(int) / AOEL
	Total	**900**	**180**	**sum**

* It is assumed in the used TC values, that body exposure is already reduced by (protective) clothing. The use of gloves will result in an extra reduction factor of 5

Table A 50: **Input parameters and estimation of long-term worker exposure – EUROPOEM II calculator – use in Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations /Christmas trees plantation** (Pome fruits) **workwear and gloves**



WORKER EXPOSURE			**EUROPOEM II MODEL**	
form	LEPTOSAR 200 SL		**Re-entry in the field**	
a.s.	acetamiprid			
Parameter		**Value**	**Unit**	**References, comments**
Re-entry activities in the field				
AR	Application rate	0,05	kg a.s./ha	summary of intended uses
Worker				
Duration				
T		8	hours / day	default: 6 h (Europoem II)
Inhalation Exposure				without PPE
	no model available	-		
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	0,45	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3 large fruit: 0.45 (Europoem II)
Dermal Exposure		**5,4**	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure				
DA	Dermal Absorption	50	%	
	PPE-factor dermal	5		gloves*
	AOEL	1,5	mg a.s./ day	based on 70 kg bw
		Without PPE	**With PPE**	
	Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	2,700	0,540	DE(int) = DE x (DA/100)
	Total	**2,700**	**0,540**	**sum**
	% AOEL			
	Inhalation	-	-	no model available
	Dermal	180	36	%AOEL = 100 x DE(int) / AOEL
	Total	**180**	**36**	**sum**
*	It is assumed in the used TC values, that body exposure is already reduced by (protective) clothing. The use of gloves will result in an extra reduction factor of 5.			

Table A 51: Input parameters and estimation of long-term worker exposure – EUROPOEM II calculator – use in green house (Tomato, aubergine paprika) potential exposure

WORKER EXPOSURE			EUROPOEM II & DUTCH MODEL	
form	LEPTOSAR 200 SL		Re-entry in greenhouses	
a.s.	acetamiprid			
Parameter		**Value**	**Unit**	**References, comments**
Re-entry activities in greenhouses				
AR	Application rate	0,06	kg a.s./ha	summary of intended uses
Worker				
Duration				
To	Cutting	4	hours / day	default: 3 h (Dutch model)
Tsb	Sorting/ bundling	4	hours / day	default: 3 h (Dutch model)
Tt	Total duration	8	hours / day	default: 6 h (Europoem II)
Inhalation Exposure				without PPE
Task Specific Factor				
	Surrogate value (indicative)			
TF	Cutting	0,1	(mg a.s./h)/ (kg/ha)	Dutch model
TF	Sorting/ bundling	0,01	(mg a.s./h)/ (kg/ha)	Dutch model
Inhalation Exposure				
	Cutting	0,024	mg a.s./ day	IE = AR x Tc x TF
	Sorting/ bundling	0,0024	mg a.s./ day	IE = AR x Tsb x TF
	Total	**0,0264**	mg a.s./ day	sum
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	0,58	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure		**8,352**	mg a.s./ day	DE = DFR x AR x TC x Tt
Internal exposure				
IA	Inhalation Absorption	100	%	
DA	Dermal Absorption	50	%	
	PPE-factor inhalation	10		reduction factor*
	PPE-factor dermal	5		gloves**
	AOEL	1,5	mg a.s./ day	based on 70 kg bw
		Without PPE	**With PPE**	
	Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	0,026	0,003	IE(int) = IE x (IA100)
	Dermal	4,176	0,835	DE(int) = DE x (DA/100)
	Total	**4,202**	**0,838**	**sum**
	% AOEL			
	Inhalation	2	0	%AOEL = 100 x IE(int) / AOEL
	Dermal	278	56	%AOEL = 100 x DE(int) / AOEL
	Total	**280**	**56**	**sum**
*	Breathing apparatus for workers can only be used in closed areas for a relatively short period of time.			

Table A 52: Input parameters and estimation of long-term worker exposure – EUROPOEM II calculator – use in green house (Tomato, aubergine paprika) workwear and gloves

WORKER EXPOSURE			EUROPOEM II & DUTCH MODEL	
form	LEPTOSAR 200 SL		Re-entry in greenhouses	
a.s.	acetamiprid			
Parameter		**Value**	**Unit**	**References, comments**
Re-entry activities in greenhouses				
AR	Application rate	0,06	kg a.s./ha	summary of intended uses
Worker				
Duration				
To	Cutting	4	hours / day	default: 3 h (Dutch model)
Tsb	Sorting/ bundling	4	hours / day	default: 3 h (Dutch model)
Tt	Total duration	8	hours / day	default: 6 h (Europoem II)
Inhalation Exposure				without PPE
Task Specific Factor				
	Surrogate value (indicative)			
TF	Cutting	0,1	(mg a.s./h)/ (kg/ha)	Dutch model
TF	Sorting/ bundling	0,01	(mg a.s./h)/ (kg/ha)	Dutch model
Inhalation Exposure				
	Cutting	0,024	mg a.s./ day	IE = AR x Tc x TF
	Sorting/ bundling	0,0024	mg a.s./ day	IE = AR x Tsb x TF
	Total	**0,0264**	mg a.s./ day	sum
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	0,25	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure		**3,8**	mg a.s./ day	DE = DFR x AR x TC x Tt
Internal exposure				
IA	Inhalation Absorption	100	%	
DA	Dermal Absorption	50	%	
	PPE-factor inhalation	10		reduction factor*
	PPE-factor dermal	5		gloves**
	AOEL	1,5	mg a.s./ day	based on 70 kg bw
		Without PPE	**With PPE**	
	Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	0,026	0,003	IE(int) = IE x (IA100)
	Dermal	1,800	0,360	DE(int) = DE x (DA/100)
	Total	**1,826**	**0,363**	**sum**
	% AOEL			
	Inhalation	2	0	%AOEL = 100 x IE(int) / AOEL
	Dermal	120	24	%AOEL = 100 x DE(int) / AOEL
	Total	**122**	**24**	**sum**
*	Breathing apparatus for workers can only be used in closed areas for a relatively short period of time.			

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for acetamiprid

Table A 54: Input parameters considered for the estimation of longer term resident exposure – EFSA calculator - use in oilseed rape, mustard, turnip rape

Croptype	Oilseeds		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		i_AppEquip
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		i_FormVal
Buffer strip	2-3	m	i_Buffer
Application rate of the product	0,06	kg a.s./ha	i_AppRate
Concentration of active substance (in-use dilution for liquid applications)	0,3	g a.s./l	d_ConcAS
Dermal absorption of product	10,00%		i_AbsorpProduct
Dermal absorption of in-use dilution	50,00%		i_AbsorpInuse
Oral absorption	100,00%		i_AbsorpOralInuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,18	µg a.s./cm²	d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	i_Volat
Concentration in air	0,001	mg/m³	d_AirCon
Resident dermal spray drift exposure 75th percentile - adult	0,47	ml spray dilution/person	
Resident dermal spray drift exposure 75th percentile - child	0,327	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - adult	0,00010	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - child	0,00022	ml spray dilution/person	
Resident dermal spray drift exposure mean - adult	0,22318	ml spray dilution/person	
Resident dermal spray drift exposure mean - child	0,18	ml spray dilution/person	
Resident inhal. spray drift exposure mean - adult	0,00009	ml spray dilution/person	
Resident inhal. spray drift exposure mean - child	0,00017	ml spray dilution/person	
Exposure duration dermal	2	hours	d_ReExpDur
Exposure duration inhalation	24	hours	d_ReExpDurInhal
Exposure duration entry into treated crops	0,25	hours	d_ExpDurTreatCrop
Light clothing adjustment factor	18,0%		d_ClothAF
Breathing rate adult	0,23	m³/day/kg	d_BreathRAd
Breathing rate child (1-3 year old)	1,07	m³/day/kg	d_BreathRCh
Drift percentage on surface (75th percentile)	5,60%		
Drift percentage on surface (mean)	4,10%		
Turf transferable residues percentage	5,00%		d_Turf
Transfer coeff. of surface deposits-adult	7300	cm²/hour	d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm²/hour	d_ReTCCh
Saliva extraction percentage	50,00%		d_SalExt
Surface area of hands mouthed	20	cm²	d_AreaHM
Frequency of hand to mouth activity	9,5	events/hour	d_ReFreqHM
Ingestion rate for mouthing of grass per day	25	cm²	d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20,00%		d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm²/h	d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm²/h	d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm²/h	d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794	cm²/h	d_TcEntryCh

Table A 555: Estimation of longer term resident exposure towards acetamiprid according to EFSA guidance – use in oilseed rape, mustard, turnip rape

1. Total

1.1 1-3 year old child

	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0402870	0,0107000	0,0048552	0,0506250	0,0768107
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0040287	0,0010700	0,0004855	0,0050625	0,0076811
% of RVNAS	16,11%	4,28%	1,94%	20,25%	30,72%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0578400	0,0138000	0,0122640	0,1687500	0,1848071
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0009640	0,0002300	0,0002044	0,0028125	0,0030801
% of RVNAS	3,86%	0,92%	0,82%	11,25%	12,32%

Table A 56: Input parameters considered for the estimation of acute bystander exposure – EFSA calculator - use in oilseed rape, mustard, turnip rape

Croptype	Oilseeds		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		*i_AppEquip*
Formulation type	oluble concentrates, emulsifiable concentrate, etc.		
Application rate of the product	0.06	kg a.s./ha	*i_AppRate*
Buffer strip	2-3	m	*i_Buffer*
Concentration of active substance (in-use dilution for liquid applications)	0.3	g a.s./l	*d_ConcAS*
Dermal absorption of product	10.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%		*i_AbsorpInuse*
Oral absorption	100.00%		*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.18	µg a.s./cm^2	*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	*i_Volat*
Concentration in air	0.001	mg/m^3	*d_AirCon*
Bystander dermal spray drift exposure - adult	1.21	ml spray dilution/person	
Bystander dermal spray drift exposure - child	0.74	ml spray dilution/person	
Bystander inhal. spray drift exposure - adult	0.00050	ml spray dilution/person	
Bystander inhal. spray drift exposure - child	0.00112	ml spray dilution/person	
Exposure duration	2	hours	*d_ByExpDur*
Exposure duration entry into treated crops	0.25	hours	*d_ExpDurTreatCrop*
Light clothing adjustment factor	18.0%		*d_ClothAF*
Breathing rate adult	0.23	m^3/kg bw/day	*d_BreathRAd*
Breathing rate child (1-3 year old)	1.07	m^3/kg bw/day	*d_BreathRCh*
Drift percentage on surface (90th percentile)	8.50%		
Turf transferable residues percentage	5.00%		*d_Turf*
Transfer coeff. of surface deposits-adult	14500	cm^2/hour	*d_ByTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	5200	cm^2/hour	*d_ByTCCh*
Saliva extraction percentage	50.00%		*d_SalExt*
Surface area of hands mouthed	20	cm^2	*d_AreaHM*
Frequency of hand to mouth activity	20	events/hour	*d_ByFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2	*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20.00%		*d_DRP*
Transfer coefficient for entry into treated crops - ad	7500	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops - chi	2250	cm^2/h	*d_TcEntryCh*

Table A 576: Estimation of acute bystander exposure towards acetamiprid according to EFSA guidance – use in oilseed rape, mustard, turnip rape

1. Total

1.1 1-3 year old child

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0.0913560	0.0107000	0.0145350	0.0506250
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0091356	0.0010700	0.0014535	0.0050625
% of RVAAS	36.54%	4.28%	5.81%	20.25%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0.1489800	0.0138000	0.0369750	0.1687500
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0024830	0.0002300	0.0006163	0.0028125
% of RVAAS	9.93%	0.92%	2.47%	11.25%

Table A 7: Input parameters considered for the estimation of longer term resident exposure – EFSA calculator - use in cereals (wheat, rye, triticale)

Croptype	Cereals		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		i_AppEquip
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		i_FormVal
Buffer strip	2-3	m	i_Buffer
Application rate of the product	0,04	kg a.s./ha	i_AppRate
Concentration of active substance (in-use dilution for liquid applications)	0,2	g a.s./l	d_ConcAS
Dermal absorption of product	10,00%		i_AbsorpProduct
Dermal absorption of in-use dilution	50,00%		i_AbsorpInuse
Oral absorption	100,00%		i_AbsorpOralInuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,12	µg a.s./cm²	d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	i_Volat
Concentration in air	0,001	mg/m³	d_AirCon
Resident dermal spray drift exposure 75th percentile - adult	0,47	ml spray dilution/person	
Resident dermal spray drift exposure 75th percentile - child	0,327	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - adult	0,00010	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - child	0,00022	ml spray dilution/person	
Resident dermal spray drift exposure mean - adult	0,22318	ml spray dilution/person	
Resident dermal spray drift exposure mean - child	0,18	ml spray dilution/person	
Resident inhal. spray drift exposure mean - adult	0,00009	ml spray dilution/person	
Resident inhal. spray drift exposure mean - child	0,00017	ml spray dilution/person	
Exposure duration dermal	2	hours	d_ReExpDur
Exposure duration inhalation	24	hours	d_ReExpDurInhal
Exposure duration entry into treated crops	0,25	hours	d_ExpDurTreatCrop
Light clothing adjustment factor	18,0%		d_ClothAF
Breathing rate adult	0,23	m³/day/kg	d_BreathRAd
Breathing rate child (1-3 year old)	1,07	m³/day/kg	d_BreathRCh
Drift percentage on surface (75th percentile)	5,80%		
Drift percentage on surface (mean)	4,10%		
Turf transferable residues percentage	5,00%		d_Turf
Transfer coeff. of surface deposits-adult	7300	cm²/hour	d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm²/hour	d_ReTCCh
Saliva extraction percentage	50,00%		d_SalExt
Surface area of hands mouthed	20	cm²	d_AreaHM
Frequency of hand to mouth activity	9,5	events/hour	d_ReFreqHM
Ingestion rate for mouthing of grass per day	25	cm²	d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20,00%		d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm²/h	d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm²/h	d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm²/h	d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794	cm²/h	d_TcEntryCh

Table A 5~~7~~8: Estimation of longer term resident exposure towards acetamiprid according to EFSA guidance – use in cereals (wheat, rye, triticale)

1. Total

1.1 1-3 year old child

	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0268580	0,0107000	0,0032368	0,0337500	0,0547738
Total systemic exposure per kg body weight	0,0026858	0,0010700	0,0003237	0,0033750	0,0054774
% of RVNAS	10,74%	4,28%	1,29%	13,50%	21,91%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0385600	0,0138000	0,0081760	0,1125000	0,1278048
Total systemic exposure per kg body weight	0,0006427	0,0002300	0,0001363	0,0018750	0,0021301
% of RVNAS	2,57%	0,92%	0,55%	7,50%	8,52%

Table A 60: Input parameters considered for the estimation of acute bystander exposure – EFSA calculator - use in cereals (wheat, rye, triticale)

Bystander exposure for Leptosar 200 SL			
Croptype	Cereals		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		i_AppEquip
Formulation type	ioluble concentrates, emulsifiable concentrate, etc.		
Application rate of the product	0.04	kg a.s./ha	i_AppRate
Buffer strip	2-3	m	i_Buffer
Concentration of active substance (in-use dilution for liquid applications)	0.2	g a.s./l	d_ConcAS
Dermal absorption of product	10.00%		i_AbsorpProduct
Dermal absorption of in-use dilution	50.00%		i_AbsorpInuse
Oral absorption	100.00%		i_AbsorpOralinuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.12	µg a.s./cm^2	d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	i_Volat
Concentration in air	0.001	mg/m^3	d_AirCon
Bystander dermal spray drift exposure - adult	1.21	ml spray dilution/person	
Bystander dermal spray drift exposure - child	0.74	ml spray dilution/person	
Bystander inhal. spray drift exposure - adult	0.00050	ml spray dilution/person	
Bystander inhal. spray drift exposure - child	0.00112	ml spray dilution/person	
Exposure duration	2	hours	d_ByExpDur
Exposure duration entry into treated crops	0.25	hours	d_ExpDurTreatCrop
Light clothing adjustment factor	18.0%		d_ClothAF
Breathing rate adult	0.23	m^3/kg bw/day	d_BreathRAd
Breathing rate child (1-3 year old)	1.07	m^3/kg bw/day	d_BreathRCh
Drift percentage on surface (90th percentile)	8.50%		
Turf transferable residues percentage	5.00%		d_Turf
Transfer coeff. of surface deposits-adult	14500	cm^2/hour	d_ByTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	5200	cm^2/hour	d_ByTCCh
Saliva extraction percentage	50.00%		d_SalExt
Surface area of hands mouthed	20	cm^2	d_AreaHM
Frequency of hand to mouth activity	20	events/hour	d_ByFreqHM
Ingestion rate for mouthing of grass per day	25	cm^2	d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20.00%		d_DRP
Transfer coefficient for entry into treated crops - ad	7500	cm^2/h	d_TcEntryAd
Transfer coefficient for entry into treated crops - chi	2250	cm^2/h	d_TcEntryCh

Table A 61: Estimation of acute bystander exposure towards acetamiprid according to EFSA guidance – use in cereals (wheat, rye, triticale)

1.1 1-3 year old child

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0.0609040	0.0107000	0.0096900	0.0337500
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0060904	0.0010700	0.0009690	0.0033750
% of RVAAS	24.36%	4.28%	3.88%	13.50%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0.0993200	0.0138000	0.0246500	0.1125000
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0016553	0.0002300	0.0004108	0.0018750
% of RVAAS	6.62%	0.92%	1.64%	7.50%

Table A 6258: Input parameters considered for the estimation of longer term resident exposure – EFSA calculator - use in maize, sorghum, millet

Croptype	Cereals		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		i_AppEquip
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		i_FormVal
Buffer strip	2-3	m	i_Buffer
Application rate of the product	0,06	kg a.s./ha	i_AppRate
Concentration of active substance (in-use dilution for liquid applications)	0,2	g a.s./l	d_ConcAS
Dermal absorption of product	10,00%		i_AbsorpProduct
Dermal absorption of in-use dilution	50,00%		i_Absorpinuse
Oral absorption	100,00%		i_AbsorpOralInuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,18	µg a.s./cm²	d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5 *10-3Pa	Pa	i_Volat
Concentration in air	0,001	mg/m³	d_AirCon
Resident dermal spray drift exposure 75th percentile - adult	0,47	ml spray dilution/person	
Resident dermal spray drift exposure 75th percentile - child	0,327	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - adult	0,00010	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - child	0,00022	ml spray dilution/person	
Resident dermal spray drift exposure mean - adult	0,22318	ml spray dilution/person	
Resident dermal spray drift exposure mean - child	0,18	ml spray dilution/person	
Resident inhal. spray drift exposure mean - adult	0,00009	ml spray dilution/person	
Resident inhal. spray drift exposure mean - child	0,00017	ml spray dilution/person	
Exposure duration dermal	2	hours	d_ReExpDur
Exposure duration inhalation	24	hours	d_ReExpDurInhal
Exposure duration entry into treated crops	0,25	hours	d_ExpDurTreatCrop
Light clothing adjustment factor	18,0%		d_ClothAF
Breathing rate adult	0,23	m³/day/kg	d_BreathRAd
Breathing rate child (1-3 year old)	1,07	m³/day/kg	d_BreathRCh
Drift percentage on surface (75th percentile)	5,60%		
Drift percentage on surface (mean)	4,10%		
Turf transferable residues percentage	5,00%		d_Turf
Transfer coeff. of surface deposits-adult	7300	cm²/hour	d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm²/hour	d_ReTCCh
Saliva extraction percentage	50,00%		d_SalExt
Surface area of hands mouthed	20	cm²	d_AreaHM
Frequency of hand to mouth activity	9,5	events/hour	d_ReFreqHM
Ingestion rate for mouthing of grass per day	25	cm²	d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20,00%		d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm²/h	d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm²/h	d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm²/h	d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794	cm²/h	d_TcEntryCh

Table A 6359: Estimation of longer term resident exposure towards acetamiprid according to EFSA guidance – use in maize, sorghum, millet

1. Total

1.1 1-3 year old child

	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0268580	0,0107000	0,0048552	0,0506250	0,0694137
Total systemic exposure per kg body weight	0,0026858	0,0010700	0,0004855	0,0050625	0,0069414
% of RVNAS	10,74%	4,28%	1,94%	20,25%	27,77%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0385600	0,0138000	0,0122640	0,1687500	0,1756478
Total systemic exposure per kg body weight	0,0006427	0,0002300	0,0002044	0,0028125	0,0029275
% of RVNAS	2,57%	0,92%	0,82%	11,25%	11,71%

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Table A 64: Input parameters considered for the estimation of acute bystander exposure – EFSA calculator - use in maize, sorghum, millet

Bystander exposure for Leptosar 200 SL			
Croptype	Cereals		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		i_AppEquip
Formulation type	soluble concentrates, emulsifiable concentrate, etc.		
Application rate of the product	0.06	kg a.s./ha	i_AppRate
Buffer strip	2-3	m	i_Buffer
Concentration of active substance (in-use dilution for liquid applications)	0.2	g a.s./l	d_ConcAS
Dermal absorption of product	10.00%		i_AbsorpProduct
Dermal absorption of in-use dilution	50.00%		i_AbsorpInuse
Oral absorption	100.00%		i_AbsorpOralInuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.18	µg a.s./cm^2	d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	i_Volat
Concentration in air	0.001	mg/m^3	d_AirCon
Bystander dermal spray drift exposure - adult	1.21	ml spray dilution/person	
Bystander dermal spray drift exposure - child	0.74	ml spray dilution/person	
Bystander inhal. spray drift exposure - adult	0.00050	ml spray dilution/person	
Bystander inhal. spray drift exposure - child	0.00112	ml spray dilution/person	
Exposure duration	2	hours	d_ByExpDur
Exposure duration entry into treated crops	0.25	hours	d_ExpDurTreatCrop
Light clothing adjustment factor	18.0%		d_ClothAF
Breathing rate adult	0.23	m^3/kg bw/day	d_BreathRAd
Breathing rate child (1-3 year old)	1.07	m^3/kg bw/day	d_BreathRCh
Drift percentage on surface (90th percentile)	8.50%		
Turf transferable residues percentage	5.00%		d_Turf
Transfer coeff. of surface deposits-adult	14500	cm^2/hour	d_ByTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	5200	cm^2/hour	d_ByTCCh
Saliva extraction percentage	50.00%		d_SalExt
Surface area of hands mouthed	20	cm^2	d_AreaHM
Frequency of hand to mouth activity	20	events/hour	d_ByFreqHM
Ingestion rate for mouthing of grass per day	25	cm^2	d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20.00%		d_DRP
Transfer coefficient for entry into treated crops - ad	7500	cm^2/h	d_TcEntryAd
Transfer coefficient for entry into treated crops - chi	2250	cm^2/h	d_TcEntryCh

Table A 6510: Estimation of acute bystander exposure towards acetamiprid according to EFSA guidance – use in maize, sorghum, millet

1.1 1-3 year old child

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0.0609040	0.0107000	0.0145350	0.0506250
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0060904	0.0010700	0.0014535	0.0050625
% of RVAAS	24.36%	4.28%	5.81%	20.25%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0.0993200	0.0138000	0.0369750	0.1687500
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0016553	0.0002300	0.0006163	0.0028125
% of RVAAS	6.62%	0.92%	2.47%	11.25%

Table A 6~~0~~: Input parameters considered for the estimation of longer term resident exposure – EFSA calculator - use in soybean and pumpkin

Croptype	Legume vegetables/ Brassica vegetables		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		*i_FormVal*
Buffer strip	2-3	m	*i_Buffer*
Application rate of the product	0,06	kg a.s./ha	*i_AppRate*
Concentration of active substance (in-use dilution for liquid applications)	0,3	g a.s./l	*d_ConcAS*
Dermal absorption of product	10,00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50,00%		*i_AbsorpInuse*
Oral absorption	100,00%		*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,18	µg a.s./cm²	*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	*i_Volat*
Concentration in air	0,001	mg/m³	*d_AirCon*
Resident dermal spray drift exposure 75th percentile - adult	0,47	ml spray dilution/person	
Resident dermal spray drift exposure 75th percentile - child	0,327	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - adult	0,00010	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - child	0,00022	ml spray dilution/person	
Resident dermal spray drift exposure mean - adult	0,22318	ml spray dilution/person	
Resident dermal spray drift exposure mean - child	0,18	ml spray dilution/person	
Resident inhal. spray drift exposure mean - adult	0,00009	ml spray dilution/person	
Resident inhal. spray drift exposure mean - child	0,00017	ml spray dilution/person	
Exposure duration dermal	2	hours	*d_ReExpDur*
Exposure duration inhalation	24	hours	*d_ReExpDurInhal*
Exposure duration entry into treated crops	0,25	hours	*d_ExpDurTreatCrop*
Light clothing adjustment factor	18,0%		*d_ClothAF*
Breathing rate adult	0,23	m³/day/kg	*d_BreathRAd*
Breathing rate child (1-3 year old)	1,07	m³/day/kg	*d_BreathRCh*
Drift percentage on surface (75th percentile)	5,60%		
Drift percentage on surface (mean)	4,10%		
Turf transferable residues percentage	5,00%		*d_Turf*
Transfer coeff. of surface deposits-adult	7300	cm²/hour	*d_ReTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm²/hour	*d_ReTCCh*
Saliva extraction percentage	50,00%		*d_SalExt*
Surface area of hands mouthed	20	cm²	*d_AreaHM*
Frequency of hand to mouth activity	9,5	events/hour	*d_ReFreqHM*
Ingestion rate for mouthing of grass per day	25	cm²	*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20,00%		*d_DRP*
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm²/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm²/h	*d_TcEntryCh*
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm²/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops (mean) - child	1794	cm²/h	*d_TcEntryCh*

Table A 67.11: Estimation of longer term resident exposure towards acetamiprid according to EFSA guidance – use in soybean and pumpkin

1. Total

1.1 1-3 year old child

	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0402870	0,0107000	0,0048552	0,0506250	0,0768107
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0040287	0,0010700	0,0004855	0,0050625	0,0076811
% of RVNAS	16,11%	4,28%	1,94%	20,25%	30,72%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0578400	0,0138000	0,0122640	0,1687500	0,1848071
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0009640	0,0002300	0,0002044	0,0028125	0,0030801
% of RVNAS	3,86%	0,92%	0,82%	11,25%	12,32%

Table A 68: Input parameters considered for the estimation of acute bystander exposure – EFSA calculator - use in soybean and pumpkin

Bystander exposure for Leptosar 200 SL			
Croptype	Brassica vegetables		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		*i_AppEquip*
Formulation type	ioluble concentrates, emulsifiable concentrate, etc.		
Application rate of the product	0.06	kg a.s./ha	*i_AppRate*
Buffer strip	2-3	m	*i_Buffer*
Concentration of active substance (in-use dilution for liquid applications)	0.3	g a.s./l	*d_ConcAS*
Dermal absorption of product	10.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%		*i_AbsorpInuse*
Oral absorption	100.00%		*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.18	µg a.s./cm^2	*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	*i_Volat*
Concentration in air	0.001	mg/m^3	*d_AirCon*
Bystander dermal spray drift exposure - adult	1.21	ml spray dilution/person	
Bystander dermal spray drift exposure - child	0.74	ml spray dilution/person	
Bystander inhal. spray drift exposure - adult	0.00050	ml spray dilution/person	
Bystander inhal. spray drift exposure - child	0.00112	ml spray dilution/person	
Exposure duration	2	hours	*d_ByExpDur*
Exposure duration entry into treated crops	0.25	hours	*d_ExpDurTreatCrop*
Light clothing adjustment factor	18.0%		*d_ClothAF*
Breathing rate adult	0.23	m^3/kg bw/day	*d_BreathRAd*
Breathing rate child (1-3 year old)	1.07	m^3/kg bw/day	*d_BreathRCh*
Drift percentage on surface (90th percentile)	8.50%		
Turf transferable residues percentage	5.00%		*d_Turf*
Transfer coeff. of surface deposits-adult	14500	cm^2/hour	*d_ByTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	5200	cm^2/hour	*d_ByTCCh*
Saliva extraction percentage	50.00%		*d_SalExt*
Surface area of hands mouthed	20	cm^2	*d_AreaHM*
Frequency of hand to mouth activity	20	events/hour	*d_ByFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2	*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20.00%		*d_DRP*
Transfer coefficient for entry into treated crops - ad	7500	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops - chi	2250	cm^2/h	*d_TcEntryCh*

Table A 6912: Estimation of acute bystander exposure towards acetamiprid according to EFSA guidance – use in soybean and pumpkin

1. Total

1.1 1-3 year old child

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0.0913560	0.0107000	0.0145350	0.0506250
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0091356	0.0010700	0.0014535	0.0050625
% of RVAAS	36.54%	4.28%	5.81%	20.25%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0.1489800	0.0138000	0.0369750	0.1687500
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0024830	0.0002300	0.0006163	0.0028125
% of RVAAS	9.93%	0.92%	2.47%	11.25%

Table A 7013: Input parameters considered for the estimation of longer term resident exposure – EFSA calculator - use in apple, pear, quince, medlar (Pome fruits), cherry, peach, nectarine, apricot, plum (stone fruits) and hazelnut, walnut (tree nuts)

Croptype	Pome fruits/Stone fruits/Tree nuts		
Application method	Upward spraying		
Application equipment	Vehicle-mounted		*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		*i_FormVal*
Buffer strip	5	m	*i_Buffer*
Application rate of the product	0,025	kg a.s./ha	*i_AppRate*
Concentration of active substance (in-use dilution for liquid applications)	0,125	g a.s./l	*d_ConcAS*
Dermal absorption of product	10,00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50,00%		*i_AbsorpInuse*
Oral absorption	100,00%		*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,075	µg a.s./cm^2	*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	*i_Volat*
Concentration in air	0,001	mg/m^3	*d_AirCon*
Resident dermal spray drift exposure 75th percentile - adult	5,63	ml spray dilution/person	
Resident dermal spray drift exposure 75th percentile - child	1,689	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - adult	0,00210	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - child	0,00164	ml spray dilution/person	
Resident dermal spray drift exposure mean - adult	3,68	ml spray dilution/person	
Resident dermal spray drift exposure mean - child	1,11	ml spray dilution/person	
Resident inhal. spray drift exposure mean - adult	0,00170	ml spray dilution/person	

Resident inhal. spray drift exposure mean - child	0,00133	ml spray dilution/person	
Exposure duration dermal	2	hours	*d_ReExpDur*
Exposure duration inhalation	24	hours	*d_ReExpDurInhal*
Exposure duration entry into treated crops	0,25	hours	*d_ExpDurTreatCrop*
Light clothing adjustment factor	18,0%		*d_ClothAF*
Breathing rate adult	0,23	m^3/day/kg	*d_BreathRAd*
Breathing rate child (1-3 year old)	1,07	m^3/day/kg	*d_BreathRCh*
Drift percentage on surface (75th percentile)	15,79%		
Drift percentage on surface (mean)	11,69%		
Turf transferable residues percentage	5,00%		*d_Turf*
Transfer coeff. of surface deposits-adult	7300	cm^2/hour	*d_ReTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour	*d_ReTCCh*
Saliva extraction percentage	50,00%		*d_SalExt*
Surface area of hands mouthed	20	cm^2	*d_AreaHM*
Frequency of hand to mouth activity	9,5	events/hour	*d_ReFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2	*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20,00%		*d_DRP*
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm^2/h	*d_TcEntryCh*
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h	*d_TcEntryCh*

Table A 7163~~3~~14: Estimation of longer term resident exposure towards acetamiprid according to EFSA guidance – use in apple, pear, quince, medlar (Pome fruits), cherry, peach, nectarine, apricot, plum (stone fruits) and hazelnut, walnut (tree nuts)

1. Total

1.1 1-3 year old child

	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0867667	0,0107000	0,0105565	0,0390375	0,1066951
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0086767	0,0010700	0,0010556	0,0039038	0,0106695
% of RVNAS	34,71%	4,28%	4,22%	15,62%	42,68%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,2888000	0,0138000	0,0266651	0,1301250	0,3261068
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0048133	0,0002300	0,0004444	0,0021688	0,0054351
% of RVNAS	19,25%	0,92%	1,78%	8,68%	21,74%

Table A 72: Input parameters considered for the estimation of acute bystander exposure – EFSA calculator - use in apple, pear, quince, medlar (Pome fruits), cherry, peach, nectarine, apricot, plum (stone fruits) and hazelnut, walnut (tree nuts)

Bystander exposure for Leptosar 200 SL			
Croptype	Pome fruit		
Application method	Upward spraying		
Application equipment	Vehicle-mounted		*i_AppEquip*
Formulation type	soluble concentrates, emulsifiable concentrate, etc.		
Application rate of the product	0.025	kg a.s./ha	*i_AppRate*
Buffer strip	5	m	*i_Buffer*
Concentration of active substance (in-use dilution for liquid applications)	0.125	g a.s./l	*d_ConcAS*
Dermal absorption of product	10.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%		*i_Absorpinuse*
Oral absorption	100.00%		*i_AbsorpOralinuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.075	µg a.s./cm^2	*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	*i_Volat*
Concentration in air	0.001	mg/m^3	*d_AirCon*
Bystander dermal spray drift exposure - adult	12.9	ml spray dilution/person	
Bystander dermal spray drift exposure - child	3.87	ml spray dilution/person	
Bystander inhal. spray drift exposure - adult	0.00440	ml spray dilution/person	
Bystander inhal. spray drift exposure - child	0.00348	ml spray dilution/person	
Exposure duration	2	hours	*d_ByExpDur*
Exposure duration entry into treated crops	0.25	hours	*d_ExpDurTreatCrop*
Light clothing adjustment factor	18.0%		*d_ClothAF*
Breathing rate adult	0.23	m^3/kg bw/day	*d_BreathRAd*
Breathing rate child (1-3 year old)	1.07	m^3/kg bw/day	*d_BreathRCh*
Drift percentage on surface (90th percentile)	19.89%		
Turf transferable residues percentage	5.00%		*d_Turf*
Transfer coeff. of surface deposits-adult	14500	cm^2/hour	*d_ByTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	5200	cm^2/hour	*d_ByTCCh*
Saliva extraction percentage	50.00%		*d_SalExt*
Surface area of hands mouthed	20	cm^2	*d_AreaHM*
Frequency of hand to mouth activity	20	events/hour	*d_ByFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2	*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20.00%		*d_DRP*
Transfer coefficient for entry into treated crops - ad	7500	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops - chi	2250	cm^2/h	*d_TcEntryCh*

Table A 7315: Estimation of acute bystander exposure towards acetamiprid according to EFSA guidance – use in apple, pear, quince, medlar (Pome fruits), cherry, peach, nectarine, apricot, plum (stone fruits) and hazelnut, walnut (tree nuts)

1. Total

1.1 1-3 year old child

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0.1987729	0.0107000	0.0262270	0.0390375
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0198773	0.0010700	0.0026227	0.0039038
% of RVAAS	79.51%	4.28%	10.49%	15.62%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0.6616750	0.0138000	0.0667177	0.1301250
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0110279	0.0002300	0.0011120	0.0021688
% of RVAAS	44.11%	0.92%	4.45%	8.68%

Table A 16: Input parameters considered for the estimation of longer term resident exposure – EFSA calculator - use in forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees plantations (Pome fruits)

Croptype	Pome fruit		
Application method	Upward spraying		
Application equipment	Vehicle-mounted		i_AppEquip
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		i_FormVal
Buffer strip	5	m	i_Buffer
Application rate of the product	0,05	kg a.s./ha	i_AppRate
Concentration of active substance (in-use dilution for liquid applications)	0,25	g a.s./l	d_ConcAS
Dermal absorption of product	10,00%		i_AbsorpProduct
Dermal absorption of in-use dilution	50,00%		i_AbsorpInuse
Oral absorption	100,00%		i_AbsorpOralInuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,15	µg a.s./cm²	d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	i_Volat
Concentration in air	0,001	mg/m³	d_AirCon
Resident dermal spray drift exposure 75th percentile - adult	5,63	ml spray dilution/person	
Resident dermal spray drift exposure 75th percentile - child	1,689	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - adult	0,00210	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - child	0,00164	ml spray dilution/person	
Resident dermal spray drift exposure mean - adult	3,68	ml spray dilution/person	
Resident dermal spray drift exposure mean - child	1,11	ml spray dilution/person	
Resident inhal. spray drift exposure mean - adult	0,00170	ml spray dilution/person	
Resident inhal. spray drift exposure mean - child	0,00133	ml spray dilution/person	
Exposure duration dermal	2	hours	d_ReExpDur
Exposure duration inhalation	24	hours	d_ReExpDurInhal
Exposure duration entry into treated crops	0,25	hours	d_ExpDurTreatCrop
Light clothing adjustment factor	18,0%		d_ClothAF
Breathing rate adult	0,23	m³/day/kg	d_BreathRAd
Breathing rate child (1-3 year old)	1,07	m³/day/kg	d_BreathRCh
Drift percentage on surface (75th percentile)	15,79%		
Drift percentage on surface (mean)	11,69%		
Turf transferable residues percentage	5,00%		d_Turf
Transfer coeff. of surface deposits-adult	7300	cm²/hour	d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm²/hour	d_ReTCCh
Saliva extraction percentage	50,00%		d_SalExt
Surface area of hands mouthed	20	cm²	d_AreaHM
Frequency of hand to mouth activity	9,5	events/hour	d_ReFreqHM
Ingestion rate for mouthing of grass per day	25	cm²	d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20,00%		d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm²/h	d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm²/h	d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm²/h	d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794	cm²/h	d_TcEntryCh

Table A ~~67~~517: Estimation of longer term resident exposure towards acetamiprid according to EFSA guidance – use in Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees plantations (Pome fruits)

1. Total

1.1 1-3 year old child

	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,1735334	0,0107000	0,0114083	0,0421875	0,1668911
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0173533	0,0010700	0,0011408	0,0042188	0,0166891
% of RVNAS	69,41%	4,28%	4,56%	16,88%	66,76%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,5776000	0,0138000	0,0288168	0,1406250	0,5248843
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0096267	0,0002300	0,0004803	0,0023438	0,0087481
% of RVNAS	38,51%	0,92%	1,92%	9,38%	34,99%

Table A 76: Input parameters considered for the estimation of acute bystander exposure – EFSA calculator - use in forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees plantations (Pome fruits)

Bystander exposure for Leptosar 200 SL			
Croptype	Pome fruit		
Application method	Upward spraying		
Application equipment	Vehicle-mounted		*i_AppEquip*
Formulation type	soluble concentrates, emulsifiable concentrate, etc.		
Application rate of the product	0.05	kg a.s./ha	*i_AppRate*
Buffer strip	5	m	*i_Buffer*
Concentration of active substance (in-use dilution for liquid applications)	0.25	g a.s./l	*d_ConcAS*
Dermal absorption of product	10.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%		*i_AbsorpInuse*
Oral absorption	100.00%		*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.15	µg a.s./cm^2	*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	*i_Volat*
Concentration in air	0.001	mg/m^3	*d_AirCon*
Bystander dermal spray drift exposure - adult	12.9	ml spray dilution/person	
Bystander dermal spray drift exposure - child	3.87	ml spray dilution/person	
Bystander inhal. spray drift exposure - adult	0.00440	ml spray dilution/person	
Bystander inhal. spray drift exposure - child	0.00348	ml spray dilution/person	
Exposure duration	2	hours	*d_ByExpDur*
Exposure duration entry into treated crops	0.25	hours	*d_ExpDurTreatCrop*
Light clothing adjustment factor	18.0%		*d_ClothAF*
Breathing rate adult	0.23	m^3/kg bw/day	*d_BreathRAd*
Breathing rate child (1-3 year old)	1.07	m^3/kg bw/day	*d_BreathRCh*
Drift percentage on surface (90th percentile)	19.89%		
Turf transferable residues percentage	5.00%		*d_Turf*
Transfer coeff. of surface deposits-adult	14500	cm^2/hour	*d_ByTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	5200	cm^2/hour	*d_ByTCCh*
Saliva extraction percentage	50.00%		*d_SalExt*
Surface area of hands mouthed	20	cm^2	*d_AreaHM*
Frequency of hand to mouth activity	20	events/hour	*d_ByFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2	*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20.00%		*d_DRP*
Transfer coefficient for entry into treated crops - ad	7500	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops - chi	2250	cm^2/h	*d_TcEntryCh*

Table A 7718: Estimation of acute bystander exposure towards acetamiprid according to EFSA guidance – use in Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees plantations (Pome fruits)

1.1 1-3 year old child

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0.3975458	0.0107000	0.0283433	0.0421875
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0397546	0.0010700	0.0028343	0.0042188
% of RVAAS	159.02%	4.28%	11.34%	16.88%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	1.3233500	0.0138000	0.0721013	0.1406250
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0220558	0.0002300	0.0012017	0.0023438
% of RVAAS	88.22%	0.92%	4.81%	9.38%

Table A 78: Input parameters considered for the estimation of acute bystander exposure – EFSA calculator - use in forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees plantations (Pome fruits) – drift reduction

Bystander exposure for Leptosar 200 SL			
Croptype	Pome fruit		
Application method	Upward spraying		
Application equipment	Vehicle-mounted-Drift Reduction		*i_AppEquip*
Formulation type	oluble concentrates, emulsifiable concentrate, etc.		
Application rate of the product	0.05	kg a.s./ha	*i_AppRate*
Buffer strip	5	m	*i_Buffer*
Concentration of active substance (in-use dilution for liquid applications)	0.25	g a.s./l	*d_ConcAS*
Dermal absorption of product	10.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	50.00%		*i_Absorpinuse*
Oral absorption	100.00%		*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.15	µg a.s./cm^2	*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	*i_Volat*
Concentration in air	0.001	mg/m^3	*d_AirCon*
Bystander dermal spray drift exposure - adult	12.9	ml spray dilution/person	
Bystander dermal spray drift exposure - child	3.87	ml spray dilution/person	
Bystander inhal. spray drift exposure - adult	0.00440	ml spray dilution/person	
Bystander inhal. spray drift exposure - child	0.00348	ml spray dilution/person	
Exposure duration	2	hours	*d_ByExpDur*
Exposure duration entry into treated crops	0.25	hours	*d_ExpDurTreatCrop*
Light clothing adjustment factor	18.0%		*d_ClothAF*
Breathing rate adult	0.23	m^3/kg bw/day	*d_BreathRAd*
Breathing rate child (1-3 year old)	1.07	m^3/kg bw/day	*d_BreathRCh*
Drift percentage on surface (90th percentile)	19.89%		
Turf transferable residues percentage	5.00%		*d_Turf*
Transfer coeff. of surface deposits-adult	14500	cm^2/hour	*d_ByTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	5200	cm^2/hour	*d_ByTCCh*
Saliva extraction percentage	50.00%		*d_SalExt*
Surface area of hands mouthed	20	cm^2	*d_AreaHM*
Frequency of hand to mouth activity	20	events/hour	*d_ByFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2	*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20.00%		*d_DRP*
Transfer coefficient for entry into treated crops - ad	7500	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops - chi	2250	cm^2/h	*d_TcEntryCh*

Table A 9719: Estimation of acute bystander exposure towards acetamiprid according to EFSA guidance – use in Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees plantations (Pome fruits) – drift reduction

1. Total

1.1 1-3 year old child

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0.1987729	0.0107000	0.0141716	0.0421875
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0198773	0.0010700	0.0014172	0.0042188
% of RVAAS	79.51%	4.28%	5.67%	16.88%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0.6616750	0.0138000	0.0360506	0.1406250
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0110279	0.0002300	0.0006008	0.0023438
% of RVAAS	44.11%	0.92%	2.40%	9.38%

A 3.4 Combined exposure calculations

Not relevant. Product contains 1 active only.

Appendix 4 Detailed evaluation of exposure and/or DFR studies relied upon (KCP 7.2. KCP 7.2.1.1. KCP 7.2.2.1. KCP 7.2.3.1)

No studies have been submitted.